

A population-based screening program for early detection of common cancers among women in India – methodology and interim results

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Correspondence to: Dr. Gauravi A. Mishra, E-mail: gauravi2005@yahoo.co.in**Abstract**

BACKGROUND: Cancers of the uterine cervix, breast, and oral cavity accounted for 134,420, 115,251, and 24,375 cases, respectively, and were responsible for 52.8% of the total cancers among women in India in 2008. **AIM:** The major objectives were to create awareness regarding common cancers among women, to detect pre-cancers of the uterine cervix and oral cavity, and early cancers of the breast, uterine cervix, and oral cavity, by conducting screening with simple, low-cost technology, within the community, and to facilitate confirmation of diagnosis among the screen positives and treatment and follow-up among the diagnosed cases. **SETTINGS AND METHODS:** This is a community-based screening program for early detection of breast, uterine cervix, and oral cancers, being implemented among the socioeconomically disadvantaged women in Mumbai, India. The process involves selection of clusters, household surveys, health education, and screening the eligible women for breast, uterine cervix, and oral cancers, by primary healthcare workers, at a temporarily set-up clinic within the community. The program is planned to cover a 125,000 disadvantaged population in five years. **RESULTS:** Twenty-one thousand and fifteen people, with 4009 eligible women, have been covered to date. The compliance for screening for breast, cervix, and oral cavity has been 85, 70, and 88% and the screen positivity rates are 3.9, 14.9, and 3.9%, respectively. Twenty-seven oral pre-cancers, 25 cervix pre-cancers, one invasive cancer of the breast, two of the cervix, and one oral cavity cancer have been diagnosed among the screened women and all of them have complied with the treatment. **CONCLUSIONS:** The program is raising awareness about the common cancers and harms of tobacco among the disadvantaged women population in Mumbai. It is also helping in detecting pre-cancers and cancers among asymptomatic women and is assisting them in receiving treatment.

Key Words: Compliance, early detection, health education, pre-cancers, screening

Introduction

Globally, breast and uterine cervix cancers are the two most common cancers among women.^[1] Even as breast cancer remains the most common cancer among women globally, a striking difference is noted between women from the developed and developing countries with respect to cancer of the uterine cervix, which still remains the most common cancer affecting Indian women. Oral cavity cancer is the fourth most common cancer among Indian women, preceded by cervix uteri, breast, and ovary. There have been 134,420, 115,251, and 24,375 cases of uterine cervix, breast, and oral cavity cancers, respectively, accounting for 52.8% of the total cancers among women in India, in 2008. These three cancers have been responsible for 142,968 deaths, accounting for 45.8% of the total cancer deaths among Indian women.^[1]

The National Cancer Control Program was formulated by the Department of Health and Family Welfare, Government of India, in 1975-1976. The major priority areas were health education for primary prevention, early detection of common cancers by screening, education on self-examination, and strengthening the existing cancer treatment facilities, including incorporation of palliative care.^[2] However, to date, there has been no organized cancer screening program across the country. Screening in India remains mainly opportunistic, with the consequence that a majority of the cancers are diagnosed at advanced stages of the disease. Only 25.1% of breast cancers, 21.7% of uterine cervix cancers, and 17.5% of oral cavity cancers (among men and women) have been diagnosed when the disease is still localized.^[3]

In India, there are approximately 948,900 new cancer cases and 633,500 deaths annually.^[1] This large scale morbidity and mortality of cancer is easily reversible with well-planned cancer education, organized screening, and early detection programs. The standard methods and technologies utilized for screening cancers in developed countries (e.g., cytology for cervix and mammography for breast cancer screening) are not directly applicable to developing countries like India, due to resource constraints and absence of trained manpower. Hence, simple, socially and culturally acceptable, cost-effective technologies need to be developed for organized cancer screening in the Indian scenario. Several such screening tests for the early detection of common cancers and methods of implementing the same at the community level are being tested in various parts of India.^[4-8] One such initiative is the current program initiated to create awareness of common cancers, detecting pre-cancers of the cervix and oral cavity, and early cancers of the breast, cervix, and oral cavity, by conducting screening with the use of simple, low-cost technology [viz., naked eye oral visual inspection (OVI), i.e., thorough oral mucosal examination, by examining the inside of the mouth, Clinical Breast Examination (CBE), visual inspection of the cervix after application of 5% Acetic Acid (VIA), and Lugol's Iodine (VILI)] by trained primary healthcare workers (PHW), facilitating confirmation of diagnosis among the screen positives, and treatment and follow-up of the diagnosed cases.

Materials and Methods

The present project is a community-based service program for screening of common cancers among women, designed to cover 125,000 people residing in low socioeconomic areas of Mumbai, India, in a time period of five years. The program design [Figure 1] is as follows:

Slum areas in Mumbai, unexposed to any cancer education or screening activity, are selected. Intricate area maps are drawn [Figure 2] and meetings are held with the administrative, social, political, and religious leaders to enlist their support.

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The Medical Social Workers (MSWs) visit each house in the area, allotting a house number, which is painted near the door. A house-to-house survey is conducted in the selected clusters to collect baseline information and a list of eligible women is compiled. The potential camp places for conducting the interventions are identified.

All women residing in the selected slum clusters were included in the study. Among these, women between 30 and 65 years were eligible for breast and cervix cancer screening, while women of any age who were current or past tobacco users, who had consumed tobacco for at least three consecutive years were eligible for oral cancer screening. The exclusion criterion was any woman with a history of cervix, breast, or oral cavity cancers.

The MSWs of the project, visit the houses of registered eligible women, interview and record the sociodemographic details, and then invite them for the Health Education Program (HEP). The community-based HEPs are conducted with the aid of posters and Flip charts [Figure 3]. The contents of a HEP includes introduction to the anatomy and physiology of the oral cavity, breast, and reproductive organs; information about the risk factors; methods for primary prevention; early signs and symptoms; methods for early detection and secondary prevention of these three cancers; teaching Breast Self Examination (BSE); and information is given on the difficulties in the treatment of advanced stages of these three cancers. Women are then invited to participate in the screening, after obtaining written informed consent. The consent form is read out and the left hand thumb impression is sought from illiterate women. Another woman from the same area witnesses the procedure and signs as a witness. After recording the height and weight, each woman is assigned a unique identity number (UIN) and photographed holding her UIN-plate. She also receives a project identity card, with her photograph affixed, and is informed about the usage of the project identity card at the Tata Memorial Hospital (TMH), in case she develops any signs or symptoms of breast, cervix, or oral cavity cancers. All the investigations for diagnostic confirmations and treatment of these cancers are provided free of cost to the registered woman.

Community-Based Screening for Breast, Cervix, and Oral Cavity Cancers

After obtaining informed consent, the eligible women are invited to participate in the community-based screening conducted by the PHWs, at a temporary clinic setup within the area. Women eligible for oral, breast, and cervix cancer screening are examined by the OVI, CBE, and visual examination methods of VIA and VILI, respectively.

Women who screened positive (according to the predefined criteria) during the primary screening at the community-based screening camps are referred to the Department of Preventive Oncology, at the Nodal Hospital for a further diagnostic workup. Those screened positive for oral lesions undergo OVI by a specialist, and if required, a cytology or biopsy of these lesions. They are enrolled at the tobacco cessation clinic for counseling on tobacco-cessation. Those screened positive for breast cancer undergo CBE by

a specialist, Mammography/Sonography, and if required, fine needle aspiration cytology (FNAC) or biopsy at the referral hospital. Similarly, cervix screen positives undergo cytology, colposcopy, and directed biopsies, for diagnostic confirmation. Women diagnosed with pre-cancers and cancers are managed as per the Evidence-Based Management guidelines at the Nodal Hospital,^[9-11] free of cost.

Various categories of staff, mainly MSWs, PHWs, data management staff, and Medical Officers (MOs) were recruited and trained to conduct the project activities. The MSWs conduct surveys, introduce informed consent, deliver HEP, and collect the sociodemographic details. The PHWs examine the women, record the findings, and send reminders to screen positive and diagnosed cases, to ensure regular follow-ups at the referral hospital. The MSWs recruited for the project are graduates, while the PHWs have tenth-grade education. The staff receives intensive training for three months, to conduct their assigned activities. The PHWs receive training to perform CBE using the modified version of the Canadian National Breast Screening Study protocol,^[12] VIA using the International Agency for Research on Cancer (IARC) manual and chart,^[13] and OVI using the IARC digital manual.^[14] For the quality check, the MOs re-examine almost all the cases labeled screen positive and around 10% of those labeled screen negatives by PHWs. The PHWs and MOs refer the women independently, irrespective of the finding of the other.

The data is recorded in the MYSQL version 2.11.6. Checks for data consistency are conducted in MYSQL and Intercooled Stata 8.2. Data analysis, on an intention-to-treat basis, is done using Stata. This article presents the initial findings of the screening program on completion of screening, in five project clusters.

Results

At present, the program activities have been completed in five slum clusters and the present article presents the analysis. The total population of the five slum clusters was 21,015, comprising of 10,967 (52.2%) males and 10,048 (47.8%) females. Three thousand six hundred and seventy-eight (36.6%) women were in the 30 to 65 years age group and were eligible for breast and cervix cancer screening. One thousand eight hundred and twenty-nine women (18.2% of the total female population) in the selected clusters consumed tobacco and were eligible for oral cancer screening. The distribution of the sociodemographic and reproductive characteristics among those eligible is shown in Table 1. The mean age of the eligible women was 42.8 years. Sixty-four percent of the women participants had school education (SSC) and the majority (90%) had a monthly family income of less than Rs. 10,000 per month. They were predominantly (83%) Hindus, mainly (80%) Marathi speaking, and mostly (79%) home makers by occupation. Eighty-two percent of the women participants were married, with the mean age at marriage being 18.7 years. Sixty-one percent were pre-menopausal, 34% post-menopausal, and the rest (5%) peri-menopausal. The

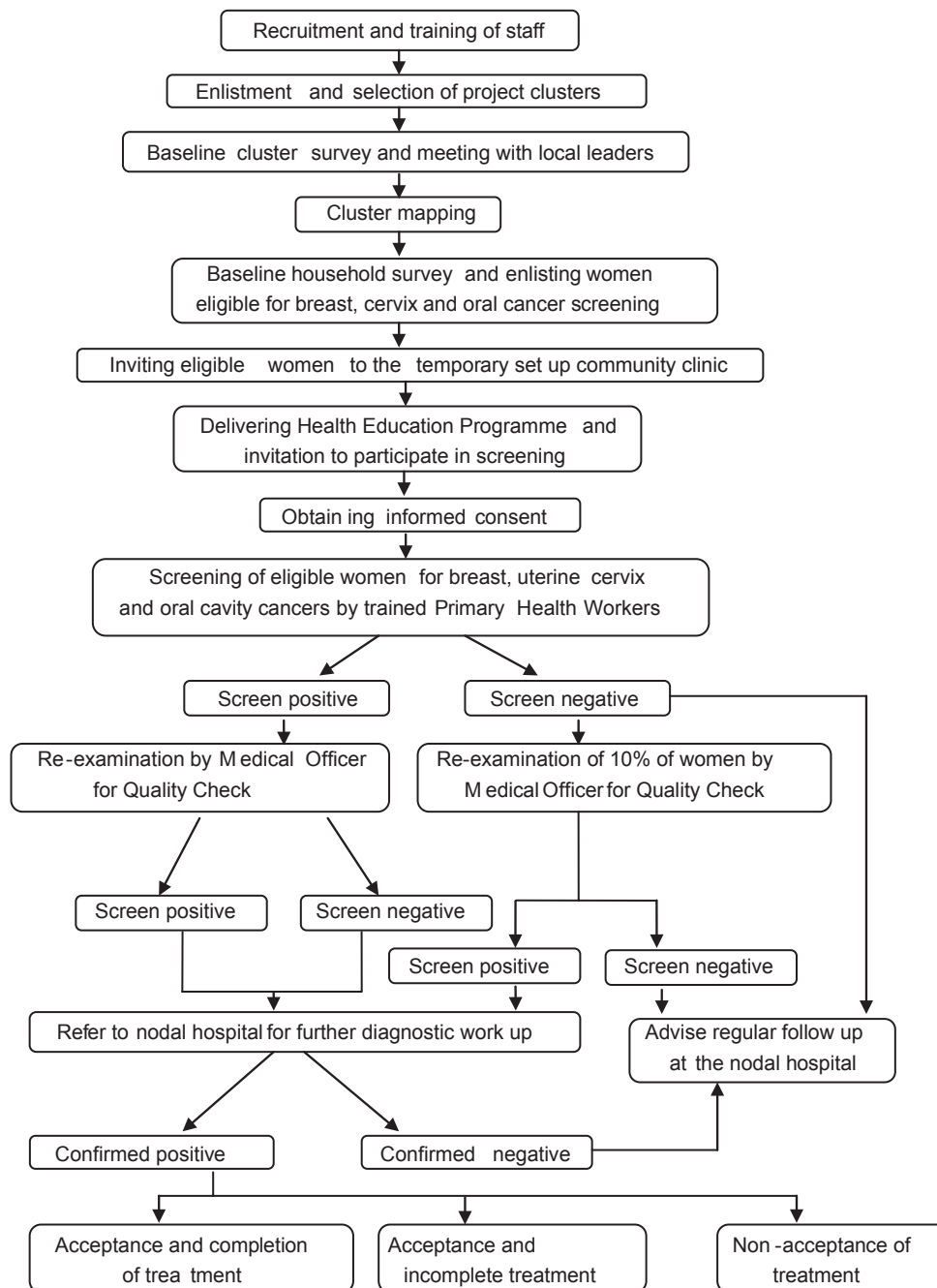


Figure 1: Flow chart of the project design

mean age at menarche and menopause was 13.8 years and 44.0 years, respectively. Women pregnant at least once made up 93.9% and 92.5% had given birth to at least one live child. The mean age of the women at first child birth was 20.7 years and the majority had three children. Almost all of them (99.7%) had breast fed their children. Each woman had breast fed her child for a total of 48 months. Even as 10.5% of the women gave a positive family history of cancer, only 0.6% had ever participated in any previous cancer screening.

All eligible women were invited to a temporary clinic within the community to participate in HEP and screening. The women screened positive were referred to the Nodal Hospital for diagnostic confirmation and management. The compliance of the eligible women to these various project activities is as shown in Table 2.

Among the 4009 eligible women enrolled, 3761 (93.8%) could be contacted, and were invited for HEP and screening. Three thousand four hundred and thirty-seven (85.7%) of them participated in the HEP. The compliance for screening of breast, uterine cervix, and oral cavity cancers were 85, 70, and 88% and the screen positivity rates were 3.9, 14.9, and 3.9%, respectively. Among those screened positive, 76.0, 73.6, and 75% of the women complied with the referral for breast, uterine cervix, and oral cavity, respectively. Twenty-five cervix pre-cancers (21 CIN I and four CIN II) and 27 oral pre-cancers (23 leukoplakias, one erythroplakia, two submucous-fibrosis (SMF), and one suspicious growth, which on biopsy was dysplasia) were diagnosed among the referred women. In addition one invasive cancer of the breast, two of the uterine cervix, and one of the oral cavity have been diagnosed among them. Even as 92 and 100% of the

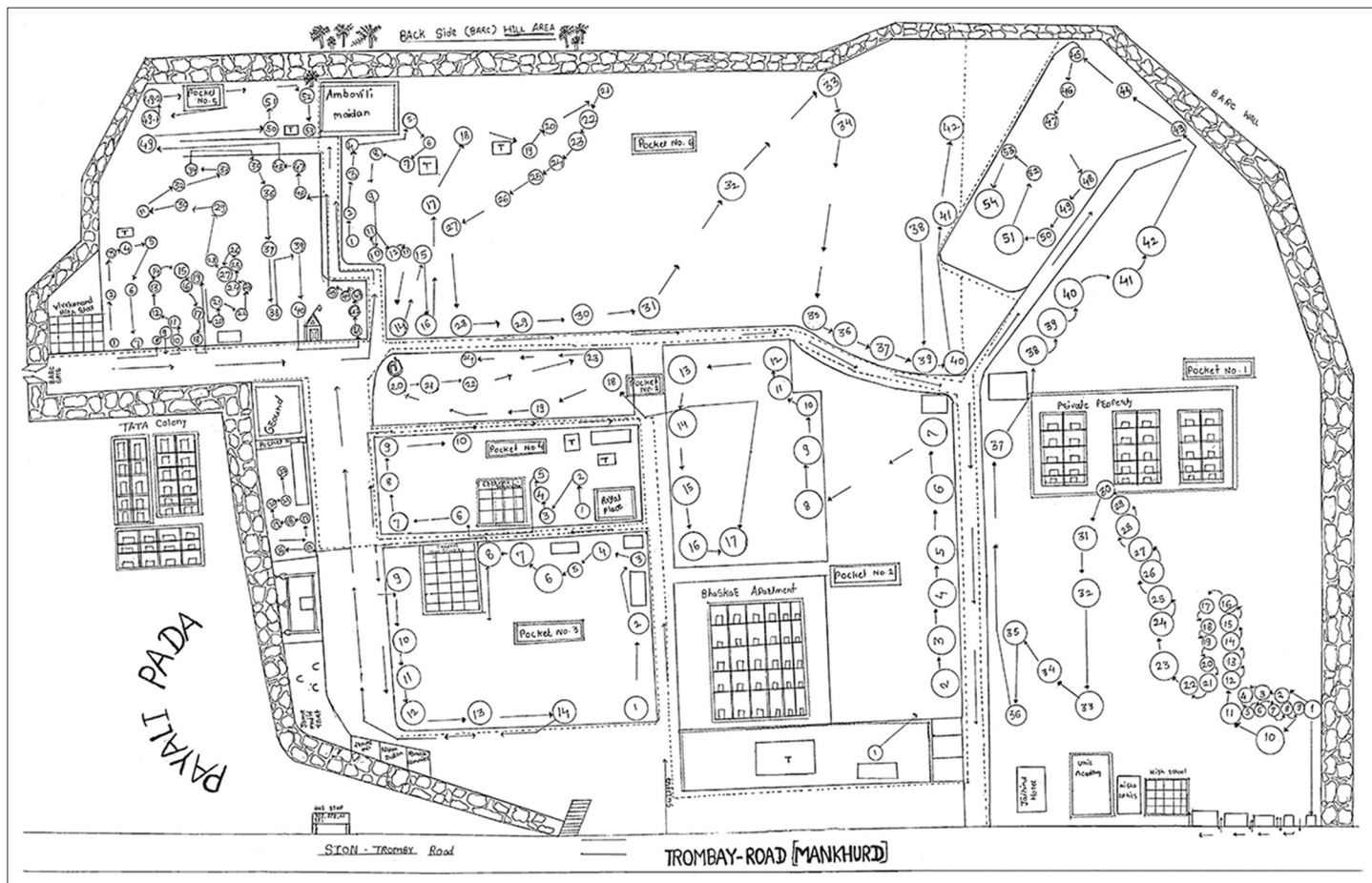


Figure 2: Intricate map of a cluster



Figure 3: Community-based Health Education Program

women complied with the treatment for uterine cervix and oral pre-cancers, respectively, 100% complied with the treatment for invasive breast, uterine cervix, and oral cavity cancers. The Medical Officers re-examined 9.4, 17.6, and 06.4% of the women examined by the PHWs for breast, uterine cervix, and oral cancers, respectively. The kappa values for agreement between the findings recorded by the PHWs and the Medical Officers for breast, cervix, and oral screening were 0.89 (0.83 - 2.52), 0.62 (0.55 - 1.70), and 0.77 (0.65 - 2.04), which translates to an agreement rate of 95, 80, and 88%, respectively.

Discussion

Four thousand and nine (19%) women from the total population of the selected slum clusters were eligible for at least one of the three cancer screenings. Among these, 248 (6.2%) women could not be contacted when the temporary clinics for screening were set up in the community despite repeated attempts, as they had either gone to their village or for work or out for various reasons. In the present program, all the cancer screening tests used were of low cost. Excellent compliance was achieved at all levels, in terms of participation of eligible women in the HEP, in screening, for diagnostic confirmation, and for treatment completion. The women participants had a very poor awareness of cancer, its risk factors, prevention, and screening methods. Hence, HEP was important to make them aware of this and increase their participation in screening. Among the eligible women, 3761 were contacted and 3437 (91.4%) participated in the HEP. In a previous study in Mumbai, nearly 91% of the women participated in the community-based HEP.^[15] In the present program, after HEP, the women were invited to participate in screening. The compliance to screening for breast, uterine cervix, and oral cancers was 85, 70, and 88%, respectively. The compliance for breast cancer screening with CBE was 76% in the first round, in a Randomized Controlled Trial (RCT), in Mumbai,^[15] 90.2% in Trivandrum^[16] and 92% in

Table 1: Distribution by important sociodemographic variables

Variables	Number of participants
Age groups (%)	
<18 years	3 (0.07)
18–29 years	199 (04.96)
30–34 years	740 (18.46)
35–39 years	820 (20.45)
40–44 years	685 (17.09)
45–49 years	578 (14.42)
50–54 years	346 (08.63)
55–59 years	255 (06.36)
60–64 years	259 (06.46)
65–79 years	106 (02.65)
≥80 years	18 (0.45)
Mean age in years (SD)	42.75 (10.76)
Education (%)	
Illiterate	1017 (27.04)
School (upto SSC)	2424 (64.45)
High school undergraduates	266 (07.07)
Graduates and above	54 (01.44)
Monthly family income (%)	
Less than Rs. 2000	169 (04.49)
Rs. 2001–5000	1792 (47.65)
Rs. 5001–10000	1429 (38.00)
Rs. 10001–15000	296 (07.87)
Over Rs. 15000	75 (01.99)
Occupation (%)	
Housewife	2970 (78.97)
Manual labor	238 (06.33)
Self-employed	326 (08.67)
Service	227 (06.03)
Religion (%)	
Hindu	3121 (82.98)
Muslim	464 (12.34)
Buddhist	125 (03.32)
Others	51 (01.36)
Language (%)	
Marathi	2995 (79.63)
Hindi	428 (11.38)
Urdu	102 (02.72)
Others	236 (06.27)
Marital status (%)	
Unmarried	116 (03.08)
Married	3093 (82.24)
Widowed	485 (12.90)
Divorced	33 (0.88)
Separated	34 (0.90)
Menstrual status (%)	
Pre-menopausal	2307 (61.34)
Post-menopausal	1273 (33.85)
Peri-menopausal	181 (04.81)
Mean age at marriage (SD)	
18.72 years (4.01), Median: 18	
Mean age at menarche (SD)	
13.82 years (1.18), Median: 14	
Mean age at menopause (SD)	
43.95 years (5.19), Median: 45	

Contd...

Table 1: Contd...

Variables	Number of participants
Mean age at first child birth (SD)	
20.73 years (3.65), Median: 20	
Average number of children	
2.85 (1.40), Median: 3	
Average total duration of breast feeding (SD)	
57.90 months (34.69), Median: 48	
History of breast feeding (%)	
Yes	3467 (99.66)
No	12 (0.34)
Family history of cancer (%)	
Yes	396 (10.53)
No	3365 (89.47)
Previous participation in screening	
Yes	23 (0.61)
No	3738 (99.39)

*The total number of women in each variable category differs as a result of missing information about a few participants on the respective variable. History of breast feeding was computed only among women with live births

the Philippines.^[17] The compliance for breast cancer screening, with mammography, varied widely. A survey performed in 2002, in the United States, among women aged 40 years and older, reported that 61.5% women had a mammogram within the preceding year.^[18] Similarly, in Los Angeles 70% of the women participated in mammographic screening.^[19] The compliance for cervix cancer screening with PAP test was 72.9%,^[7] with an HPV DNA test was 74%,^[7] and with visual screening methods was 71.5%, in Mumbai^[15] and between 56.4 and 79% in the trials conducted in different Indian regions.^[7,8,20,21] The compliance in the first screening round in a community-based oral cancer screening trial in South India was 73 and 89% among males and females, respectively.^[22]

The screen positivity rate with CBE for breast was 3.9%, with visual screening methods for cervix was 14.9%, and with OVI for oral cancer screening was 3.9%, in the present study. However, the screen positivity rate was 1.0%^[23] with CBE in a study in Mumbai, 5.7%^[16] in Trivandrum, and 2.5% in Philippines study.^[17] The screen positivity rate for cervix cancer with visual screening was 1.6% in a previous study in Mumbai,^[23] 14% in the Osmanabad district of India,^[7] and 9.6% in South India.^[5] In South India, 7.3% of the tobacco users examined by OVI had screened positive in the first round.^[22] The compliance for further diagnostic investigations among women screened positive was 76% for breast, 74% for cervix, and 75% for oral in the present study. The compliance for diagnostic investigations among the screen positives for breast was 73% in Mumbai^[23] and only 35% in the Philippines.^[17] It was 79% for cervix in Mumbai^[23] and 63% for oral in Kerala.^[16] Twenty-seven oral pre-cancers and 25 cervix pre-cancers, in addition to two invasive cancers of the cervix, one of the breast, and one of the oral cavity have been diagnosed among the participating women. A majority have complied with the treatment.

Table 2: Compliance to health education, screening, and referral

Cluster	Eligible women	Women contacted (% of eligibles)	Participation in health education (% of eligibles)	Site	Eligible women	Compliance to screening (%)	Screening+ve (% of screened)	Compliance to referral (% of screen positives)	Pre-cancers	Cancers
1	1337	1284 (96.04)	1177 (88.03)	Br	1278	1114 (87.17)	45 (4.04)	38 (84.44)	-	-
				Cx	1278	938 (73.40)	120 (12.79)	94 (78.33)	7	1
				Oral	426	386 (90.61)	19 (4.88)	17 (89.47)	12	-
2	616	584 (94.81)	526 (85.39)	Br	562	480 (85.41)	21 (4.38)	17 (80.95)	-	-
				Cx	562	375 (66.73)	78 (20.8)	63 (80.77)	2	1
				Oral	281	255 (90.75)	9 (3.14)	7 (77.78)	2	1
3	720	675 (93.75)	593 (82.36)	Br	685	565 (82.48)	36 (6.37)	28 (77.78)	-	1
				Cx	685	468 (68.32)	97 (20.73)	57 (58.76)	7	-
				Oral	236	210 (88.98)	18 (8.57)	13 (72.22)	7	-
4	521	478 (91.75)	434 (83.30)	Br	464	382 (82.33)	10 (2.62)	5 (45.45)	-	-
				Cx	464	319 (68.75)	36 (11.29)	24 (66.67)	5	-
				Oral	325	272 (83.69)	12 (4.41)	5 (41.67)	2	-
5	815	740 (90.80)	707 (86.75)	Br	691	586 (84.80)	9 (1.54)	4 (44.44)	-	-
				Cx	691	470 (68.02)	51 (10.87)	43 (84.31)	4	-
				Oral	568	497 (87.50)	6 (1.21)	6 (100)	4	-
Total	4009	3761 (93.81)	3437 (85.73)	Br	3680	3127 (84.97)	121 (3.87)	92 (76.03)	-	1
				Cx	3680	2570 (69.84)	382 (14.87)	281 (73.56)	25	2
				Oral	1836	1620 (88.24)	64 (3.94)	48 (75)	27	1

The simple, low-cost technologies used for screening in this program are and have been studied in several trials in low-income countries.^[4-8,16] The proof of their efficacy is also emerging from various regions. The primary objective of initiating this service program in Mumbai was to establish that the same tests would work equally well in a real program setting.

The interim analysis suggests that the methodology of program delivery was successful in reaching a large number of the previously unscreened population. Acceptability of the program was excellent and a considerable number of cancer and pre-cancer cases had been detected in a totally asymptomatic population. This program, when completed, would demonstrate the successful organization of a screening program, in its totality, in low-income urban areas of the developing world.

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