ABSTRACT

Background: In view of the increasing burden of cancers in developing countries and this study was conducted to first understand community needs and perceptions, secondly to design and implement evidence based preventive strategies, and lastly to test the short-term outcome of these strategies in the field.

Study Design: Cross Sectional mixed methods before and after intervention community based study. The study had three phases. Phase I involved understanding perceptions, attitudes and practices and needs assessment using qualitative and quantitative methods, gaining from the strengths of both by combining the approaches. Based on the findings of Phase I, appropriate comprehensive interventions were designed and implemented in Phase II. A repeat survey using quantitative methodology was conducted to assess the short-term impact of the intervention. The primary outcome was change in perceptions, attitudes and contextual health care seeking practices among the community.

Results: Results of this study will be reported in peer-reviewed publications and in conference presentations

Conclusion: This first of its kind study in India has helped in understanding the determinants of perceptions, attitude and practices regarding cancer in the community, which helped in formulating need based intervention strategies. Testing the short-term outcome of intervention showed it to be effective. The study will help in policy decision making by the planners and administrators of the state.

Keywords: Cancers, Mixed methods, Protocol, Behaviour, Intervention

INTRODUCTION

Cancers refer to a group of diseases sharing similar characteristics and may affect all cells in the body irrespective of ages and gender. They are multifactorial in causation. Environmental exposures, specific infections and genetic predisposition have been implicated in carcinogenesis and tobacco has been identified as the most important risk factor. The diagnosis and management require a combination of community based and health care facility based activities including utilization of advanced diagnostic and treatment modalities involving huge financial burden. Cancer control requires the effective implementation of preventive, promotive, treatment and rehabilitative approaches. Additionally, palliative care is required for improving quality of life of patients in incurable terminal stages. In the context of limited resources in LMIC countries like India, appropriate planning, strategies and their effective implementation can lead to remarkable results in prevention, early diagnosis and management with considerable benefits in terms of disease burden, mortality and finances.

It is estimated that there are 2.4 million cancer pa-
patients in India with 0.8 million new cases in a year. It is now the third major cause of death with 0.4 million deaths per annum and the age standardized incidence rate of cancers per 100,000 is 100.4 among men and 109.3 among women. With increasing longevity, urbanization and changes in lifestyle the incidence of cancer is increasing rapidly. It is estimated by WHO that by the year 2020 the number of cases of cancer will double in developing countries. In India, it was noted that approximately 30% of cancer cases in men are related to the Lung, Larynx and Oral cavity (all tobacco related) with about 25% cervical cancer and a further 30% breast cancer in females. Tobacco-related cancers are amenable to primary prevention (48% in men, 20% in women), oral cancers can be diagnosed early and treated successfully, 13% cervical cancers and 9% of breast cancers in women can be detected early and treated.

However, most cancers in India present in advanced stages when only palliative care can be offered, 40-50% cannot benefit from curative therapy due to this delayed presentation. Of the patients who come to the hospitals, cancer outcome depends on the stage of cancer e.g. cervical cancer is 100% curable in stage I, while stage III/IV cervical cancer only 35-50% five-year survival rates are found. The cost of treatment is very high for an individual and a huge financial burden to the nation. Most of these cases are preventable, if the level of awareness is improved about these cancers amongst the public and primary level health care professionals.

India does not have a uniform cancer prevention strategy for the entire country. Few states have undertaken IEC/BCC activities but a uniform standardized strategy for the same is lacking. Sporadic attempts have been made for cancer screening that too in very few parts of the country. Thus, current strategy of National Cancer Control Programme has not shown any significant impact. Whereas, a combination of campaigns-vertical approach and horizontal programmes, are being used presently for other health programmes like HIV/AIDS and cervical cancer and a further 30% breast cancer in females. Tobacco-related cancers are amenable to primary prevention (48% in men, 20% in women), oral cancers can be diagnosed early and treated successfully, 13% cervical cancers and 9% of breast cancers in women can be detected early and treated.

Interventions to increase knowledge and early reporting have been conducted in developed countries. These interventions could be divided into individual level and community level, with varying results and outcomes but with common theme of the interventions being effective despite limited evidence. Later studies have clearly shown these to be much more effective. However in-depth studies for formulating evidence based comprehensive and effective programme for prevention and early detection of common cancers utilizing a multi-pronged awareness intervention strategy targeting community, health care workers and cancer control program functionaries are lacking in India. Furthermore, the effect of implementation of such interventions have not been studied leading to paucity of information for planners for making evidence based decisions for National Cancer Control Program (NCCP). Hence this community based intervention trial was conducted to first understand community needs and perceptions, secondly to design and implement evidence based preventive strategies, and lastly to test the short-term outcome of these strategies in the field. The aim was to provide evidence based data to programme planners and an eventual goal of decreasing human suffering and the burden of cancer utilizing a multi-pronged awareness intervention strategy.

METHODS

A mixed methods approach was utilized to assess community needs, design appropriate interventions and assess their short-term impact. Combination of qualitative and quantitative methods has been the subject of heated debate with purists in both camps arguing against this union. In recent times, use of two methods in combination has gained popularity and there are different ways in which the two techniques can be combined. Qualitative techniques when used before quantitative can be used to provide much needed information when venturing into new areas, to check assumptions and refine research questions is valuable across and within cultures. The two can be used together in the same study to extend and complement findings and both types of information together provide a better basis for planning strategies for prevention. We utilized a combination of these methods in Phase I of our study.

Selection of Study Sites: Three districts of Delhi were selected by a random process after listing all the districts of Delhi. Two randomly selected districts out of these three were intervention districts and one district was used as control (Fig 1).
FIG 1: Map of Delhi, India depicting the three chosen districts for the study and 75 clusters examined across the three selected districts of Delhi during the quantitative surveys.

FIG 2: Study Design

The study was divided into three phases (Fig 2). The Phase I of the study included quick assessment of facilities (part one), community needs assessment utilizing qualitative (part two) as well as quantitative (part three) methods. Part I involved assessment of resources and methods available for implementation of the intervention. Part II, Qualitative assessment was carried out to assess the perceptions of the community on cancer. Part III involved Quantitative assessment of the knowledge, perceptions and practices of the community regarding common cancers. Phase II involved implementation of the intervention and again had two parts. In Part I, the intervention was designed based on Qualitative and Quantitative assessment findings of Phase I. Part II dealt with the actual implementation of the intervention in two districts of Delhi. Phase III, post intervention assessment was carried out using quantitative methods.

Phase I - Part I

A quick survey using rapid assessment procedures (RAP) was done in each district to record facilities and infrastructure available with special emphasis on the program implementation issues like availability of facilities, manpower, equipment, supplies, training, client conveniences, outreach, referral mechanism, monitoring and feedback mechanisms, etc. Cancer statistics for these areas were also collected and analyzed from cancer registry.

Mapping of all the existing health centers of government, private and NGO sectors was done and listed. Interaction with NGOs and voluntary organization working in these districts was done. Information regarding survey and project implementation in the district was conveyed to local administration to seek their permission. All the listed organization of the particular district were intimated about the cancer awareness project and were requested to participate. The MCD clinics, CGHS and other dispensaries were also approached.

Phase I - Part II

Qualitative assessment of the perceptions of the community on cancer was conducted to incorporate the findings for structuring effective cancer control programme. It was designed to understand common perceptions and their determinants, sociocultural beliefs in the community, and also to know issues of availability, affordability, accessibility and acceptability of services influencing clients’ behavior. The need of training among health care providers were also assessed in understanding and assessing their perceptions and practices regarding the cancer control programme.

Psychological and behavioral research plays an important role in cancer prevention and control. Scientific evidence to date indicates that thoughts and behavior can have a significant impact on cancer onset and course and vice-versa. Psychological aspects also influence adherence to screening pro-
grams or treatment modalities. The assessment of perceptions of community and development of their behaviour regarding common cancers helped us in establishing evidence based activities for prevention and early diagnosis of cancer. A methodology based on RAP (Rapid assessment procedure) was used as it permits quick and systematic data collection. This approach synthesizes multiple sources of information to rationalize and objectively balance evidence. Data were collected through in depth interviews and Focus Group Discussions (FGDs) with all categories of stakeholders identified for the study.

Study Population: The key issue was the representative nature of the study population for RAP (Rapid assessment procedure). There is always a trade-off between research duration, quantity and accuracy of data collected. Principles of optimal ignorance and appropriate imprecision are acceptable and necessary for such qualitative methods. Purposive sampling was done keeping in view the convenience and quality of data collection. In each district one non slum area and one slum cluster was picked up by the random process after listing all such non slum area and slum cluster of that particular district. Programme planner and manager were interviewed at the Delhi project headquarter.

Identification of study subjects: Out of the selected three districts, at least one stakeholder from non slum and slum area was interviewed. Community members were stratified according to age and in each category at least two stakeholders were interviewed. Thus, a total of 108 stakeholders were interviewed in three districts of Delhi along with officer in charge NCD in MCD, making a total of 109 in-depth interviews. Details of in depth interviews have been provided in Table 1. A total of 6 FGDs were conducted. Three with community members (one in each district- two in slum and one in a non-slum area). Three interviews with nurses and compounds and social workers (one in each district). Thus, a total of 109 in depth interviews and 6 focus group discussions were conducted.

Development of Study Instruments: A multidisciplinary team comprising of clinicians, social scientists, public health specialist and epidemiologist formulated the study instruments after multiple discussions. The instrument was open ended and pre-tested.

Quality Assurance Measures: All measures were taken to ensure the collection of valid and reliable data, including: training of the Research Associates (social science background); supervision of first 30% interviews by the senior investigators trained in interview techniques; recording of all interviews; updation of all transcripts; surprise visits during data collection; data triangulation; cross checking of coding and domain identification.

Method triangulation: In addition to in depth interviews, focus group discussions were conducted with community and health workers. Thus, responses obtained through the two methods facilitated comparison for consistency of information.

Data triangulation

Internal consistency: There were multiple questions in every questionnaire probing the same domains dealing with critical study objectives.

Between stakeholder consistency: Responses from various stakeholders were matched for confirmation.

Data Analysis

The data were cleaned on the basis of transcribed text. The responses were free listed and grouped into domains that emerged from free listed responses. Thereafter the free listed responses were coded into domains and entered into the computer and data analyzed in consonance with objectives of the study. Atlast as well as manual approach were used for analysis.

Outcome

Planners need in depth unbiased information on the community they serve and on the health-related behavior of their clients. Assessment of community perceptions regarding common cancers and also determinants of their behavior towards cancers helped in designing and implementing an appropriate, contextual IEC campaign. Thus, this psychosocial and behavioral research component of the study will be useful in planning community based interventions.

Phase I: Part III

Study Design: The sample community was selected using PPS (Probability Proportional to Population Size). Using this method, the likelihood of community being selected was in relation to the proportion of its population size. The sampling universe was a district and all three districts were included.

Sample size calculations: As per available literature, approximately 50% of individuals in the community had adequate knowledge regarding etiology, prevention and early diagnosis of common cancers. The available literature also showed that prevalence of correct attitudes and practices was much lower than the correct knowledge. Table 2 shows sample size calculations for determining all the primary outcomes. Community based short term intervention leading to only 10% increase in prevalence of KAP are also of much importance. The sample size was calculated using this as the basis because
the researchers wanted to capture even this much change. Moreover, the attitude and practices are also not expected to change more than this immediately and this sample size was appropriate to estimate the difference in the attitude and practices consequent to the intervention. To cater for refusals / semi filled questionnaires, 10% of the total was added to the calculation.

Table 1: Details of stakeholders interviewed

<table>
<thead>
<tr>
<th>Stakeholders</th>
<th>Interviews per district</th>
<th>Total interviews*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program Planners &amp; Managers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non slum</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Slum</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td># Officer in Charge NCD in MCD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Doctors, Allopathic (Minimum MBBS)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Government</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Private</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>Doctors (AYUSH)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Government</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Private</td>
<td>1</td>
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</tr>
<tr>
<td>Total</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>Nurses / Compounders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Government</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Private</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>2</td>
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<tr>
<td>MSW</td>
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<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>Facilitators</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NGO’s</td>
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<td>1</td>
</tr>
<tr>
<td>Total</td>
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<td>6</td>
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<tr>
<td>Leaders</td>
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<td>1</td>
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<tr>
<td>Total</td>
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<td>6</td>
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<tr>
<td>Community Members</td>
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<td></td>
</tr>
<tr>
<td>15-25 yrs.</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>25-35 yrs.</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>35-45 yrs.</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>45-65 yrs.</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>10</td>
<td>20</td>
</tr>
</tbody>
</table>

*Total interviews* in three districts of Delhi (Total study sample); # Officer in Charge NCD in MCD

Table 2: Calculation of Sample size

<table>
<thead>
<tr>
<th>Primary Objective</th>
<th>p1</th>
<th>p2</th>
<th>P</th>
<th>m</th>
<th>n</th>
<th>k</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knowledge</td>
<td>0.5</td>
<td>0.6</td>
<td>0.01</td>
<td>20</td>
<td>458</td>
<td>23</td>
</tr>
<tr>
<td>Attitude</td>
<td>0.3</td>
<td>0.4</td>
<td>0.01</td>
<td>20</td>
<td>458</td>
<td>23</td>
</tr>
<tr>
<td>Practices</td>
<td>0.1</td>
<td>0.2</td>
<td>0.01</td>
<td>20</td>
<td>458</td>
<td>23</td>
</tr>
</tbody>
</table>

*p = ICC; m = size of cluster (number of respondents) k = number of clusters (m / n)

The number of subjects required per group (intervention and control) to test the hypothesis of this study were calculated using the software "Acluster" which is specific for design and analysis of cluster based studies in health research. Due to metropolitan nature, each colony in Delhi comprises of heterogeneous mix of people. The intra class correlation co-efficient for each cluster could safely be presumed to be very low. Table 2 shows that the number of clusters required per group was 23 if 20 subjects are interviewed per cluster. For the sake of convenience, 25 clusters were selected in each group (each district) and 20 subjects chosen from each cluster. These 20 subjects were from the age group of 15-49 years. Out of which, 10 were males and 10 females. Thus, a total sample of 500 in each District was studied in pre-intervention phase and similar number was studied in the post intervention phase. Table 3 shows the total sample size for the study.

Method of drawing clusters: PPS method was used to draw clusters and a colony was taken as a cluster. Sampling universe was a district of Delhi. The data were arranged in separate columns. The first column listed the name of the colonies (i.e. the community); second column, the total population of the colony; and the third cumulative population. The sampling interval was obtained by dividing the total population of the zone by the number of clusters desired. A random number between one and the sampling interval was chosen as the starting point and the sampling interval was added regularly to the random number until the desired number of clusters was chosen. The selected clusters were plotted on a map of respective districts and a logical sequence (route map) for the fieldwork was developed for each of the survey teams.

Method of selecting study subjects: Within each cluster, a central point / important landmark (e.g. place of worship, community hall, etc.) was chosen. An empty bottle was spun on the ground, once it stopped spinning, the direction of open end of bottle was taken by the male Health Attendant (HA) for selection of male study subjects. The female HA moved in opposition direction for selection of female study subjects.

The first available, unlocked house was chosen and available male member (age 15-49 years) selected. In case of more than one male member in the household the eldest was chosen. Only one male from one household was included in the study. After interviewing, the male HA then moved to next house in same direction and next unlocked house was chosen. This process was repeated till 10 males were interviewed. The female HA followed the same procedure, but in different direction. The refusals were recorded.
Tools: Pre-tested and validated (validity testing including construct validity was carried out during pilot) tools (assessment sheets, questionnaires - close ended) were used for this study for rapid assessment involving all stakeholders and activities of the programme. Same instruments were utilized for pre and post phases of the study and also for the intervention as well as control areas.

Statistical analysis details have been provided in phase III.

Phase II – Part I

Resources were developed and existing material modified after the needs based community assessment. Awareness messages were tailored as per the need of the community/target group keeping educational, socioeconomic background in mind. Help from professional groups was sought for designing the awareness messages. The intervention was designed keeping in mind three specific age groups: Children 11-18 years (enrolled in school and not enrolled in school); males and females 19-45 years; and males and females more than 45 years of age. A frame work for the group discussion format was developed to maintain uniformity and quality control. Posters, pamphlets, hoardings, CDs, talks, interpersonal communication points were prepared and campaigns were planned. A group of health workers from government and private hospitals were provided training for demonstration of OSE and BSE. Various issues in teaching and use of audio visual media were fine-tuned and finalized before implementation.

Phase II- Part II (Actual Implementation of the Intervention (18 Months))

Community related activities: Focused and concerted awareness messages were propagated in the community. Interpersonal communication (IPC), posters, banners and pamphlets were used to inform people regarding the campsites and timings. IPC was used at the campsites. While doing so, utmost care was taken regarding the medium of IEC material used and the target audience. After an intensive awareness campaign, cancer awareness camps were organized in the respective areas. Each camp included awareness activities regarding common cancers and their prevention and screening for early detection. Video shows /street play were arranged on the campsites. People were educated regarding procedure for self-examination of various cancers, and peoples’ concerns and questions were answered.

Health care worker (HCW) related activities: All HCWs in the health care facilities mapped were involved in the implementation.

Strategies: An optimum combination of group contact approach and personal contact approach was used. The awareness related to common cancers was created using all channels of communication i.e. interpersonal communication, print material, audio-visual aids, etc (whichever best suited to the locality or the target group based on the assessments in Phase I of the study).

Cancer awareness and early detection: Existing health facility based screening of breast, cervical and oral cancers was organized only after effective level of awareness was achieved. Referral and transport for further evaluation and treatment was an in-built priority.

Specific activities carried out in intervention districts: Group discussion: Group discussions were organized at schools, colleges and community levels on harmful effects of tobacco and common cancers. A group of students, and health workers were trained for organizing group discussions at different levels to involve a large number of people.

Awareness activities: Awareness activities were conducted to make the people aware on cancer related topics. Multi lingual pamphlets, posters were displayed at all the important places of the district. Same were distributed and displayed at all the clinics, dispensaries and hospitals. Hoardings with information on common cancers were displayed at prominent places.

Anti-smoking campaigns: These were intensified throughout the district. Information on harmful effects of tobacco, second hand smoke, etc., were displayed in public areas. Enforcement of ‘no smoking’ laws were discussed with the local administration. All the public places and no smoking areas were prominently marked and boards displayed in concordance with school, college community norms.

Street plays, skits: Groups of students, members from community were encouraged to organize small skits on tobacco, cancer at schools, colleges and community at frequent intervals. A professional agency was hired to conduct street plays at the same topic. Street plays and skits were intensified during health camps and festive occasions.

Teaching of Self-examination methods (Oral and Breast):Posters, hand bills on self-examination methods with pictorial references were displayed in all clinics, dispensaries and hospitals. Handbills were distributed at educational institutions and offices. Audio visual medium was also used to demonstrate the same to patients.

Door to door campaign: Door to door campaign was conducted for dissemination of information on cancer to cover the population which is restricted at home or does not visit public places very fre-
The difference in knowledge, attitude, perceptions and practices of the community and health care workers regarding common cancers was assessed as part of short term evaluation. Later, a long-term evaluation can be carried out in these areas by comparing cancer related statistics over a period of 5-10 years in the same areas. This data can be collected from Cancer registry at IRCH, AIIMS.

**Short term Evaluation:** Evaluation of the activities was done by post testing in a representative sample of same area, where pre-testing was done, and also by few specific outcome indicators measuring community participation, social mobilization and health service utilization. For the purpose of uniform representation of the community utilizers and non-utilizers of the camp facility were assessed. Outcome indicators were change in level of knowledge; self-prevention activities like use of tobacco, etc.; use of screening facilities; use of health care centers for cancer related issues by the community. Changes in: referral mechanism; client conveniences; HCWs attitudes and practices; supplies were also assessed.

**Statistical analysis:** A database was created in MS Access and analysis conducted using SPSS Ver 13 and STATA ver 10. Initially, phase I quantitative data were analyzed as per objectives. Later, comparisons were made between pre and post intervention in the intervention areas and the control area. Appropriate statistical tests were used as per the scales of measurement and distribution. Comparison of intervention and control areas were also carried out before and after the intervention \(^{13}\). Hierarchical modeling of the data was done for evaluating the effects of intervention. A \(p\) value of less than 0.05 was considered significant.

**RESULTS**

Results of this study will be published in peer-reviewed journals and presented during conferences.

**DISCUSSION**

The study has helped in understanding the determinants of perceptions, attitude and practices regarding cancer in the community. This, helped in formulating the need based intervention strategies. Testing the short-term outcome of intervention showed it to be effective. The study is a first of its kind in India, in designing, implementing and testing the effectiveness of strategies in the community and will help in policy decision making by the planners and administrators of the state.

Applied value of the study: It has involved an extensive exercise to scrutinize, assess, intervene and reassess the ground level problems impeding positive awareness and knowledge of common preventable cancers, to enable the common man to seek appropriate medical care and health measures for preventing such cancers. Our investigations and multi-pronged stratified intervention strategies have yielded several useful tools, techniques and information to reinforce larger full-scale national and local cancer prevention programs being implemented across India. The benefits which can be accrued from this study are as per succeeding paras.

Value addition & Resources: We have garnered several unique and novel perspectives of cancer prevention and the dynamics that regulate such health oriented activities in the community. The insight that we have gained from the various impeding and reinforcing factors that interplay to affect cancer awareness, knowledge of preventive and corrective actions, and appropriate health seeking behavior, have enabled us to innovate and develop suitable tools, strategies, and resources to assist cancer awareness and preventive activities in the field. These resources encompass a range of audio-visual tools, human resource training material, novel ideas for street plays, radio and TV campaign, and educational material for school and college students.

**Novel Implementable Data:** Our extensive research exercise encompassing qualitative and quantitative interviews spread across more than 75 clusters and colonies in three districts of Delhi, has generated essential field data which reveals multiple facets of the level of cancer awareness, knowledge, health seeking behavior and practices in communities of Delhi. This information can be readily utilized by ongoing and future cancer prevention programs and national health authorities for better structuring and implementation of national and local cancer programs.

**Field Training & Human resource Development:** Human resource development and manpower training has been an integral part of our study. We...
delivered detailed training programs for empowering health care workers, social workers, paramedics and field workers across all ranks from government and non-government organizations. These bodies include CGHS, MCD, NDMC, and various NGOs. All training has been conducted by experienced preventive oncologists and hematologists to ensure quality impact. All training modules had the advantage of incorporating and addressing the various new aspects of cancer awareness and prevention which we have elucidated through our studies and which have been poorly addressed hitherto.

Strategy Validation and Policy reinforcement: One of the key achievements of this research program is validation and standardization of effective cancer prevention and awareness augmentation strategies. Congruent to our defined research objectives we undertook stratified statistical analysis of every intervention strategy deployed by us, in light of the type of population, socioeconomic strata, age groups, gender, level of education, regional and cultural cohorts etc.

CONFLICT OF INTEREST

None declared. This study was fully funded by the Indian Council of Medical Research (ICMR), New Delhi, India vide project entitled “Community based planned intervention for the change in perception and health seeking behavior of cancers in Delhi: A pilot study”, Number : I-589, from Apr 2009 to Dec 2012

ETHICS: Ethics approval had been granted by the IEC of All India Institute of Medical Sciences (AIIMS), New Delhi, India.

REFERENCES