Cervical Cancer
Prevention Screening and Treatment
A Pilot Initiative of Tamil Nadu Health Systems Project

By
Tamil Nadu Health Systems Project
Department of Health and Family Welfare, Government of Tamil Nadu

Documentation Supported by:
Ministry of Personnel, Public Grievances and Pensions
Department of Administrative Reforms & Public Grievances
Government of India.
DOCUMENTATION AND DISSEMINATION OF A BEST PRACTICE

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CHAPTER 1

The Risk of Cancers

Women, especially in developing countries like India, are the pivot around which a family functions. Whether educated or uneducated, living in a village or a city, they tend to put their children and families first, often at the cost of their health. While all minor ailments are brushed under the carpet, major ones too get neglected – often not only due to negligence, but also due to lack of awareness, difficulty to access health service providers and the forbidding cost involved in screening and treatment.

Today, it has also become a fact of life that Non-Communicable Diseases (NCD) are potentially more devastating not only for the individuals and communities, but for the state and country as a whole. This has a serious impact not only on the individuals, but their families and the national economy too, directly and indirectly. Its gravity can be gauged from the fact that it accounts for 53% of disease burden. There is direct cost involved in providing expensive treatment for those affected by the disease and also the indirect impact on the overall earning power.

The prevalence of Non-Communicable Diseases (NCD), just like the communicable diseases, can be achieved with awareness creation, periodic
screening and timely intervention. But, due to lack of awareness and a natural hesitation to seek health care services, the urban poor and the rural population keep away from getting themselves checked and nip the disease in its bud.

While it is important to contain the spread of infectious or communicable diseases, it is equally important to curtail the progress of Non-Communicable Diseases especially the cancers. Breast cancer and cervical cancer have been found to be the two topmost reasons for taking the lives of women, according to several studies. They could strike anywhere, anytime. And yet, they can be prevented too, with proper screening for early detection and certain changes to lifestyle and by enhancing hygiene.

**Cervical Cancer**

As indicated earlier, cervical cancer has been identified as one of the most common cancers among women worldwide. In 2010, globally, there were 275,128 deaths and in India, approximately 72,825 women died due to cancer of the cervix. Every year, 132,082 Indian women are diagnosed with cervical cancer. Women in developing countries are most vulnerable, accounting for about 86 percent of the total cases. About 11.4 percent of women are estimated to harbour Human Papilloma Virus (HPV) infection of the cervix at a given time and 70.9 percent of invasive cervical cancers in the world are attributed to HPVs of type 16 or 18. In India, about 7.9 percent of women in the general population are estimated to harbour cervical HPV infection at a given time and 82.5 percent of invasive cancers are attributed to HPVs of type 16 or 18.

Human Papilloma Virus (HPV) infection is now identified as the causative agent leading to cervical cancer. However, in addition to this, there are other triggers that facilitate the infection to develop into a cancer. Timely screening and intervention are therefore very important to prevent its progression from infection to cancer.
The Tamil Nadu Health care policy believes that "Prevention is better than cure" and has introduced several awareness and screening programs to detect disease in asymptomatic individuals and providing services towards prevention and treatment.

Tamil Nadu Health Systems Project (TNHSP): A note

The Tamil Nadu health policy of 2003 focused on the key issues of fighting Non-Communicable Diseases, improving management of health systems and improving the health status of disadvantaged communities. The Tamil Nadu Health Systems Project (TNHSP) which began in January 2005 with support from World Bank aims to achieve these goals by strengthening oversight of the public health facilities along with greater engagement of the Non-Government (NGO) sector, increasing access to and utilization of maternal and neo-natal care services, effective implementation of Non-Communicable Disease interventions, and increasing effectiveness of service delivery in public sector hospitals at the district and sub-district levels.
In an effort to improve the oversight and Management, during the project period, TNHSP has also evolved an effective Health Management Information System that enables the project designers and implementers to track and measure project outcomes, hospital indicators and health indicators.

The first phase of TNHSP was successfully implemented during January 2005 to September 2010 and the project has been extended for another four years from October 2010 to September 2014.

**The Objective**

One of the reasons TNHSP opted to focus on cervical cancer first as a pilot initiative during 2007-10 was that the maximum number of cases in India were diagnosed in south India and Cervical Cancer ranks the top most followed by breast cancer. In recent times, three premiere medical institutions in Chennai namely Institute of Obstetrics & Gynecology (IOG), Kasturba Gandhi Hospital (KGH) and Raja Sir Ramasamy Mudaliar (RSRM) Hospital also reported high level of detection of Cancer Cervix. This clearly indicates a pressing need to spread awareness and educate women between 15 and 60 years of age on the need to change their lifestyle and become aware of risk factors behind Cervical Cancer and the importance of screening.

TNHSP realised that while treatment is important, the greater need is prevention, increase awareness about risk factors, screening services to be made available and enforce lifestyle modifications. This is possible only through achieving Behaviour Change Communications (BCC) which aims to facilitate a change in lifestyle and also encourage screening for early detection of cancer as well as timely intervention for those detected positive in screening test.

**Risk Factors:**

Typically, the factors identified as the risk factors for cancer of cervix among the women include:
• Human Papilloma Virus (HPV)
• Coitus before 18 years of age
• Multiple sexual partners
• Delivery of first baby before 20 years of age
• Multiparity (having more than one child)
• Poor personal hygiene
• Poor socio-economic status
• Tobacco use
• Drug abuse
• STD infections
• Immunosuppression
• Coinfection with HIV
• Oral contraceptive use

Pilot initiative to screen women:

Globally, it has been proved that well-organized cervical screening programs or widespread good quality cytology can reduce cervical cancer incidence and mortality. Information about sexual and reproductive health behaviours also helps healthcare service providers to design effective preventive strategies against cancer of the cervix.

Towards this end, it was decided to conduct a pilot program to screen for Cervical cancer in two districts that would serve as a learning experience before implementing the program across the state. Screening is performing a test on a usually asymptomatic individual to detect the probability of having or developing a given disease.

TNHSP started to implement the pilot program for Cervical Cancer between 2007-2010 to screen women in the target age group for cervical cancer. It identified two agricultural districts with availability of all three types of
government health care centres – Primary, Secondary and Tertiary – for this exercise. Theni and Thanjavur were found to be representative of the state for the pilot.

In the pilot, the target was to reach the message on the need for screening, screen seven lakh rural and urban poor women in the target age of 30 years and above for Cervical Cancer and treat those detected with the disease.

**Pilot Design**

Traditionally, Papanicolaou Test or the Pap Smear test has been the screening test used widely to screen for cervical cancer. But it requires a certain level of skill to take adequate smear and a cyto technician to process the specimen and a Pathologist to interpret the results. It needs proper infrastructure and well-equipped lab for testing, skilled technicians and transport facility. There is also a time delay for the report to be made ready increasing the risk of losing the patient in the meantime.

So TNHSP scouted for an alternative system that would be viable for rural conditions and easy to implement. Visual Inspection with Acetic Acid followed by Visual Inspection with Lugol’s Iodine (VIA/VILI) was a method that had been introduced and used on a small scale in India for screening cervical cancer. There have also been international experience with this method, both in developed and developing countries. TNHSP got experts to develop protocols and got it vetted by TATA Memorial Institute of Cancer, Mumbai, and Adyar Cancer Institute. The protocol was then approved by World Bank before the implementation of the protocol in the pilot programme.

VIA/VILI involves visual inspection of cervix with acetic acid and Lugols Iodine under magnification. Even a paramedical staff with minimal skills can use this method to screen and interpret the results. Also, the result is instantaneous, thus decreasing loss to follow up.
If this test suggests the individual to be at risk, she is sent to the nearby secondary care or tertiary care hospital for colposcopy to confirm the diagnosis and for Cryotherapy treatment, if it is found to be a low grade lesion.

Female doctors, staff nurses and paramedics were provided training to impart skills on VIA/VILI technique. Obstetricians and Gynaecologists were also trained in Colposcopy and Cryotherapy techniques.
CHAPTER 3

The Implementation

The pilot was conceptualised in 2005-06 and rolled out in February 2007, with the dual focus of creating awareness among the target group and bringing behavioural change, encouraging health preventive behaviour. Those identified as at risk would be sent for further test and treatment.

First the need was to create awareness among the target group of women about the screening program. The challenge was the mental block women have in accepting that they could be at risk of contracting cancer. Since the symptoms for cervical cancer in the early stage could be too mild or the risk too low for them to realise the need, the women would not feel that they were at risk making them to hesitate to go for screening.

Therefore, the awareness program was designed such that women could be contacted directly, in addition to advertisements and general awareness creation programs. For this, 469 Village Link Volunteers (VLVs), affiliated to contracted Non-Governmental Organizations (NGOs), were appointed and allocated 5000 women each. Of this, about a thousand women were in the target group. Their role was to contact the women, educate them about cervical cancer and encourage them to go for screening for Cervical Cancer.
Parallely, National Institute of Epidemiology (NIE), a technical organization of ICMR, was appointed to monitor and fine-tune the protocol as the pilot progressed. NIE provided services for concurrent evaluation of the pilot program. The Public Health Foundation of India was appointed to evaluate the cost implications. Based on the feedback and recommendations of these two organisations, the scope of the pilot would be expanded to other districts in Tamil Nadu in a phased manner.

The pilot was monitored by a team consisting of Project Director (TNHSP); Expert advisers; Deputy Director (Cervical Cancer); State Coordinator; Information, Education and Communication (IEC) Officer.

At the district level, supervision of activities was carried out by a team made up of Joint Director of Rural and Health Services (JDHS), Deputy Director of Health Services (DDHS), Dean (Medical College) for both Thanjavur and Theni districts, Cancer Control Officer (CCO), and District Project Management Officer (DPMO).

At the field level, the pilot was implemented by:

1. NGOs (14 in Thanjavur and 6 in Theni) who were responsible for providing Village Link Volunteers

2. Village Link Volunteers (VLVs)-309 in Thanjavur and 160 in Theni conducted home visits to enumerate and motivate targeted women for uptake of screening and treatment services. Counsellor Cum Assistants (CCAs) 72 in Thanjavur and 34 in Theni who were stationed at screening centres provided counselling to women in
the General Out Patient Department (OPD) for update of screening and also to those who underwent screening regarding follow up visits or referrals, wherever necessary. They also provided support services to the clinical and paramedical staff involved in screening.

3. Laboratory Technicians and Pathologists (in the two medical college selected - Thanjavur and Theni) were responsible for the histopathological investigations.

When the response to the screening was lukewarm, the CCAs played a critical role in encouraging the target women from the general OPD to go for screening. The scope of work of Village Health Nurses (VHNs) manning sub-centres was also expanded to include monitoring the functioning of VLVs and reiterating their efforts.

Panchayat heads and Municipal Councillors were also educated so that they could in turn encourage the women under their jurisdiction to undergo screening.
Pilot Programme on Screening for Cervical Cancer

Primary Screening for Cancer Cervix by VIA/VILI test

VIA/VILI Negative

VIA/VILI Positive

Colposcopic evaluation

Post menopausal women in whom SCJ is not visualized & ECC is negative can be followed up after 5 years.

Cervicitis / Squances Metaplasia to be considered as normal.

Spreading the Word

Apart from appointing VLVs and CCAs for creating awareness about screening for cancer, TNHSP also undertook IEC activities (Information, Education and Communication). Flex boards of clinical protocols were put up in the 106 screening centres and

- Information boards on Cervical Cancer screening was put up in all screening centres
• IEC materials (Brochures, Flip charts, Stickers) were supplied to VLVs, VHNs and counsellors in the two pilot districts.

• Sensitisation programmes were organised for PRIIs, Self Help Groups (SHGs), school teachers, Anganwadi workers, etc.,

• Street plays and cultural programmes were organised by VLVs

• IEC messages as scrolling were put up in local cable channels

• Awareness programmes on Cervical Cancer screening were broadcasted in FM radios.
CHAPTER 4
Successes, Challenges and Learnings

Between 2007-2010, more than 4.75 lakh women were screened for cervical cancer using VIA / VILI test. Of this, 20,000 women were found to be positive and were referred for further evaluation to higher centres. Confirmed cancer cases were provided treatment in tertiary care centres.

<table>
<thead>
<tr>
<th>Categories</th>
<th>Theni</th>
<th>Thanjavur</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of women screened</td>
<td>196559</td>
<td>291525</td>
</tr>
<tr>
<td>Total number of VIA /VILI positive</td>
<td>5090</td>
<td>15743</td>
</tr>
<tr>
<td>Total number of women underwent Colposcopy</td>
<td>3195</td>
<td>8577</td>
</tr>
<tr>
<td>Total number of satisfactory Colposcopy</td>
<td>3150</td>
<td>6909</td>
</tr>
<tr>
<td>Total Number of normal Colposcopy</td>
<td>1706</td>
<td>3451</td>
</tr>
<tr>
<td>Total Number of abnormal Colposcopy</td>
<td>1444</td>
<td>3458</td>
</tr>
<tr>
<td>Total Number of Biopsies done</td>
<td>1489</td>
<td>3856</td>
</tr>
<tr>
<td>Total Number of unsatisfactory Colposcopy</td>
<td>45</td>
<td>1668</td>
</tr>
<tr>
<td>Categories</td>
<td>Theni</td>
<td>Thanjavur</td>
</tr>
<tr>
<td>----------------------------------------------------------------------------</td>
<td>-------</td>
<td>-----------</td>
</tr>
<tr>
<td>Total Number of Endocervical Curretages done – Biopsies were done instead of ECC for 45 cases in Theni</td>
<td>0</td>
<td>479</td>
</tr>
<tr>
<td>Total number of cases reported as normal after biopsy</td>
<td>125</td>
<td>1679</td>
</tr>
<tr>
<td>Total number of cases reported as Cervicitis after biopsy</td>
<td>1123</td>
<td>1422</td>
</tr>
<tr>
<td>Total Cancer cases confirmed</td>
<td>241</td>
<td>942</td>
</tr>
<tr>
<td>Total number of cases reported as Cervical intraepithelial Neoplasia I after biopsy</td>
<td>16</td>
<td>177</td>
</tr>
<tr>
<td>Total number of cases reported as Cervical intraepithelial Neoplasia II &amp; III after biopsy</td>
<td>7+5</td>
<td>91</td>
</tr>
<tr>
<td>Total number of cases reported as Frank Invasive Cancer after biopsy</td>
<td>213</td>
<td>674</td>
</tr>
<tr>
<td>Total cases treated</td>
<td>76</td>
<td>517</td>
</tr>
<tr>
<td>Total number of Cryotherapy done</td>
<td>3</td>
<td>31</td>
</tr>
<tr>
<td>Total number of Conization done</td>
<td>0</td>
<td>6</td>
</tr>
<tr>
<td>Total number of hysterectomies done</td>
<td>30</td>
<td>180</td>
</tr>
<tr>
<td>Total number of cases treated palliatively with / without surgery – Chemotherapy &amp; Radiotherapy</td>
<td>43</td>
<td>300</td>
</tr>
<tr>
<td>Total deaths</td>
<td>48</td>
<td>83</td>
</tr>
<tr>
<td>No. of recurrence</td>
<td></td>
<td>18</td>
</tr>
</tbody>
</table>
The VIA/VILI method had proved to be a cost effective and simple screening tool in low resource settings. By strengthening the service delivery method and improving follow up of screened positive cases, the pilot demonstrated that this could be scaled up across the state as planned.

At the end of the pilot, the respective health Directorates sustained the pilot program in the two districts while preparatory activities were undertaken to upscale the program to other districts. The reporting was also to be tied up with the National Cancer Registry Programme, conducted by the Indian Council of Medical Research.

Another positive outcome has been tying this programme with the government’s Chief Minister’s Comprehensive Health Insurance Scheme (CMCHIS). This would cover surgical procedures such as hysterectomy, radical hysterectomy, bilateral pelvic node dissection (BPLND), bilateral salpingo oophorectomy, ovarian transposition, anterior exentration, posterior exentration, total pelvic exentration, supra levator exentration; palliative and supportive treatment for patients with frank cervical cancer. As a result, all cervical cancer cases can avail cashless treatment at all government and empanelled private facilities under the CMCHIS. This will encourage more women to get themselves screened and pursue treatment in case of being diagnosed positive and needing surgical/palliative treatment. This also ensures timely treatment without procedural delays and better follow up.

**Challenges and Lessons**

The cervical cancer screening program was to be implemented in a staggered manner. Initially it was decided to do a pilot in two representative districts of the state both agricultural in nature, so that the learnings from this exercise would enable the TNHSP to modify and correct its program, if required.
To understand the progress of the pilot, state level and district level coordinators were appointed and the pilot reviewed periodically. Whenever required, mid-course corrections were recommended.

It was found that geographical inaccessibility and women’s mindset were bottlenecks in making the awareness campaign a total success. And so, the IEC and Inter Personal Communication (IPC) activities were strengthened and target women motivated and counselled to undergo the screening. The role of CCAs and VHNs was also expanded to encourage the women to visit public health facilities to undergo screening.

While the focus was sharp on rural women, urban women in the pilot districts were overlooked. This was one of the reasons why the target of seven lakh could not be achieved. But realising this, the cervical cancer team included municipal hospitals in its purview. The screening programmes also involved core group population under Sexually Transmitted Diseases (STDs) taking into consideration the vulnerability of individuals with STD to HPV infections.

In the initial stages of project implementation, each district had one colposcopy centre only. This was not enough when the project took off after intensified awareness campaign and the number of women volunteering for screening increased. So for each district, colposcopy centres were increased from 1 to 3 per district. In the later phases of the project all Taluk and Non-Taluk Hospitals in the Districts were provided with Colposcopes.

Non-availability of qualified and experienced human resources at all levels, particularly Pathologists and lab technicians, was a severe limitation of the program. The field level staff (VLVs, CCAs) recruited for this purpose, were also being used for other works in the institutions. This limitation was overcome by fixing their responsibilities and intensified supervision and monitoring.
Incomplete reports, reporting errors and false reporting were also problems that were observed and the true impact would not be understood if these issues were not addressed. Reporting formats were further simplified and changed and more emphasis was laid on correct and complete recording and reporting.

Medical personnel at all levels were reluctant to participate in the project and stick to the framed protocol. Transfer of personnel at institutional, district and state level also hindered the effective implementation of the programme. Frequent sensitization on the program were conducted to address these issues.

Though obstacles threatened to derail the program, timely course corrections and addressing the issues on hand helped in making the pilot project a success. As a result, this program has been now incorporated into the routine mode in all government health institutions not only in these two districts but also upscaled to rest of the 30 districts in Tamil Nadu.

Following are the key findings learnt in the pilot:

- Difficulties in creating awareness in remote areas
- Decreased acceptability of screening by women due to fear & inaccessibility
- Non coverage of urban women
- Poor rapport between the VLVs, CCAs & VHNs
- Frequent change of personnel at all levels
- Shortage of Human Resources in the existing system diluted the services of the current personnel
- Reluctance of all the Medical Personnel at all levels
- The framed protocol not followed strictly
- Treatment of women with Cervical cancer from other districts
- Incomplete monthly reports & reporting errors
• Non availability of experienced Pathologists & regular Lab Technicians left increased biopsy turn over time

• Repeated repairs of the equipments in the lab, need for few equipments, inadequate power supply & inadequate biopsy samples

The Learnings

The challenges during the pilot phase between 2007-2010 also proved to be a time to prepare for the full-fledged implementation and upscaling of the screening program for cervical cancer across the state of Tamil Nadu.

Instead of appointing VLVs, as in the pilot, TNHSP decided to use village health nurses to spread the message of cervical cancer and the importance of early detection in prevention and treatment of the disease and also use the Self Help Group (SHG) network in the state through Rural Development Department. Though CCAs had been effective in spreading the word, that is an extra post that needs policy decision. So instead, in the Upscaling program two exclusive female staff nurses for each of the hospitals and one in each of the PHCs have been appointed dedicated for screening cervical cancer besides three other Non-Communicable Diseases (NCDs) namely Breast Cancer, Hypertension & Diabetes Mellitus.

Self help groups will also be used to spread the word. Animators – the more active members of the SHGs – will be trained to create awareness. This is expected to be effective since it will be women from their local communities who will be talking about the risks and the need for early detection.

For the IEC activities, TV advertisements and short films have been identified as the best means to reach out to a vast majority of the target population.

More colposcopy equipments have been provided to each of the secondary and tertiary care institutions so that women can reach the nearest hospital and
were also supplied to the centres to ensure that testing was not delayed on account of it.

Training and the use of information technology for noting down the details of the women screening is another area of focus to improve the information collection and data generation mechanism and to enable proper follow up.

**Cost evaluation:**

The Public Health Foundation of India conducted a cost analysis to ascertain the cost of screening per individual and the cost per detected case. The pilot has reported a probability of cervical cancer detection rate of 5.5%. The additional cost per woman screened was Rs.102 at any of the pilot facilities irrespective of the outcome of the screening. The average cost per potential case detected thus was Rs.2,260. The cost per case treated however increased significantly to Rs.4,09,413 in large measure due to the less than optimal follow-up reported during this pilot program. But this does not account for the fact that the focus of the pilot was encouraging screening and pursuing treatment.

Given the prevalence and high mortality, the cost study suggests that screening for cancer of cervix is a low cost prevention intervention for rural India, provided low cost screening can be combined with adequate follow up and treatment coverage. For further scale-up and replication of this program, better outreach and follow up measures need to be established to ensure that the benefits of the program do reach the affected. This would also lead to better cost efficiency.
CHAPTER 5

Scaling Up

The TNHSP program for creating awareness, screening and treating women with cervical cancer was also aimed to help the policy makers and administrative to understand the prevalence and profile of Cervical cancer in Tamil Nadu and device suitable Upscaling program in the state. The pilot has also helped in experience sharing with other states and also the ministry of Health and Family Welfare, Government of India.

Given the success of the pilot and the learnings that have enabled mid-course corrections for better results, the government of Tamil Nadu scaling up the implementation of the screening for cervical cancer and also expanded the scope to include breast cancer. The Phase I has begun in 16 districts (2011 - 2012) and the remaining 16 phase II districts covered during (2012 – 2013). Additional financing has been extended to Tamil Nadu Health Systems Project to sustain all activities under the NCD program.
The districts to be covered in a phased manner is presented in following table.

<table>
<thead>
<tr>
<th>Phase I districts</th>
<th>Phase II districts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chennai</td>
<td>Thiruvallur</td>
</tr>
<tr>
<td>Cuddalore</td>
<td>Thiruvannamalai</td>
</tr>
<tr>
<td>Kancheepuram</td>
<td>Vellore</td>
</tr>
<tr>
<td>Villupuram</td>
<td>Salem</td>
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<tr>
<td>Madurai</td>
<td>Nammakal</td>
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<tr>
<td>Virudhunagar</td>
<td>Krishnagiri</td>
</tr>
<tr>
<td>Sivagangai</td>
<td>Dharmapuri</td>
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<tr>
<td>Theni</td>
<td>Karur</td>
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<tr>
<td>Dindigul</td>
<td>Coimbatore</td>
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<tr>
<td>Trichy</td>
<td>Tirupur</td>
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<tr>
<td>Perambalur</td>
<td>Nilgiris</td>
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<td>Thanjavur</td>
<td>Erode</td>
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<td>Kanyakumari</td>
</tr>
<tr>
<td>Pudukottai</td>
<td>Ramanathapuram</td>
</tr>
</tbody>
</table>
CHAPTER 6
Awards & Honours

- The Project abstract has been awarded second prize in the poster presentation in the International Conference on Health Systems Strengthening by the Rajasthan Health Systems Project, in Jaipur, during the year 2008.

- The project was selected for an oral presentation at the Diabetes Summit for South East Asia, in Chennai, November 2008.

- The Project abstract has been awarded second prize in the poster display in the International Conference on Health Systems Strengthening by the Tamil Nadu Health Systems Project, in Chennai during the year 2010.

- The Project abstract was selected for an oral presentation at the National OG Conference on Colposcopy and Cryotherapy, Chennai 2010.

- The Project abstract was selected for a poster presentation in the International Conference on HPV and Cancer 2010, Amsterdam, The Netherlands.