



Guidelines for Cervical Cancer Screening Programme

18th –19th November 2005

Government of India-World Health Organization
Collaborative Programme (2004-2005)



Department of Cytology & Gynaecological Pathology
Postgraduate Institute of Medical Education
and Research, Chandigarh, India

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FOREWORD

India is one of the few countries to have a National Cancer Control Programme. The emphasis has been on prevention of tobacco related cancers, early detection and augmentation of therapeutic services and promotion of palliative care. The magnitude of the problem and the relative inadequacy of infrastructure are major challenges to be addressed. Cancer of the uterine cervix is the commonest cancer among women in India and we have the largest burden of cervical cancer patients in the world. More than three-fourths of these patients are diagnosed at advanced stages leading to poor prospects of long-term survival and cure.

Organized population based screening programmes have been shown to reduce the incidence and mortality from cervical cancer in many developed countries. Cervical cytology using Pap smear has been well established as the screening method for cervical cancer. There have been a large number of studies which have proved the effectiveness of alternate strategies such as visual inspection with acetic acid and other methods in different parts of the world including India. These approaches are found to be suitable in low resource settings and need to be studied in pilot programmes.

The Department of Cytology and Gynaecological Pathology at the Postgraduate Institute have organized a meeting of the experts and have come out with guidelines for population based screening programmes for cervical cancer in the Indian context. These are generic guidelines and investigators can adapt them to suit the available resources and manpower. Since we cannot wait to start screening programmes until all the resources are in place, we can start pilot programmes which can incorporate newer methods and these guidelines provide a detailed road map for implementing such programmes.

Evidence and experience generated from such programmes will help in substantially refining these approaches to develop a nationwide Cervical Cancer Screening programme in the near future.

(K.RAAMAMOORTHY)



Director,
Postgraduate Institute of
Medical Education and
Research, Chandigarh.

MESSAGE

I am pleased to learn that the Department of Cytology and Gynaecological Pathology, PGIMER, Chandigarh is publishing the proceedings of the WHO sponsored Expert Group meeting on "*Strategies for Cervical Cancer Control*" held in November, 2005. The experts included representatives from the Regional Cancer Centres, Federation of Obstetrics and Gynaecologists of India, Indian Academy of Cytologists, World Health Organization Office, India, as well as representatives from the International Agency for Research in Cancer, France.

The document highlights the multidisciplinary approach towards Cervical Cancer Control and prevention including the role of community and preventive oncologists, gynaecologists, pathologists, radiation oncologists and the various paramedical disciplines.

I hope the policies outlined in this document will be a step towards the control of cervical cancer in India.

(K.K. Talwar)

Acknowledgments

We gratefully acknowledge the support received from the Government of India and the World Health Organization India Country Office. The financial support for conducting the Expert Group Meeting was received vide sticker No. SE/05/410532. This meeting would not have been possible without the initiative and determination of Dr. Cherian Varghese, Cluster co-ordinator, WHO India Country Office. The Expert Group Meeting was organized by Dr. A. Rajwanshi, Head, Dept. of Cytology and Gynaecological Pathology, PGI and our sincere thanks to him.

We thank the Director, Postgraduate Institute of Medical Education and Research for his support and encouragement.

We also acknowledge Dr. R. Sankaranarayanan, Screening Group, International Agency for Research on Cancer, France who enriched the meeting with this experience.

The Proceedings of the meeting were edited into a formal document by Dr. Baridalyne Nongkynrih. Dr. Partha Basu, Dr. Radhika Srinivasan and Dr. Cherian Varghese. Our thanks to their meticulousness and untiring efforts. Thanks also to Dr. R. Nijhawan for his editorial assistance.

Finally, we thank all the participants and the institutions they represented who have made this meeting and this document possible by their valuable contributions.

List of Abbreviations

CCSP	:	Cervical Cancer Screening Programme
Colpo	:	Colposcopy
CIN	:	Cervical Intraepithelial Neoplasia
DH	:	District Hospital
HPE	:	Histopathology Examination
HW-F	:	Health Worker-Female
IEC	:	Information, Education and Communication
IUCD	:	Intra Uterine Contraceptive Device
LEEP	:	Loop Electro-surgical Excision Procedure
MO	:	Medical Officer
MPHW	:	Multipurpose Health Worker
NGO	:	Non-Government Organization
Pap	:	Papanicolaou
PHC	:	Primary Health Center
QC	:	Quality Control
RCC	:	Regional Cancer Center
SCCP	:	School for Cervical Cancer Prevention
VIA	:	Visual Inspection with Acetic Acid
VILI	:	Visual Inspection with Lugol's Iodine

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CERVICAL CANCER

I. INTRODUCTION

Cancer of the uterine cervix is the second most common cancer among women world-wide. In India this is the commonest cancer among women and this country has the largest burden of cervical cancer patients in the world.

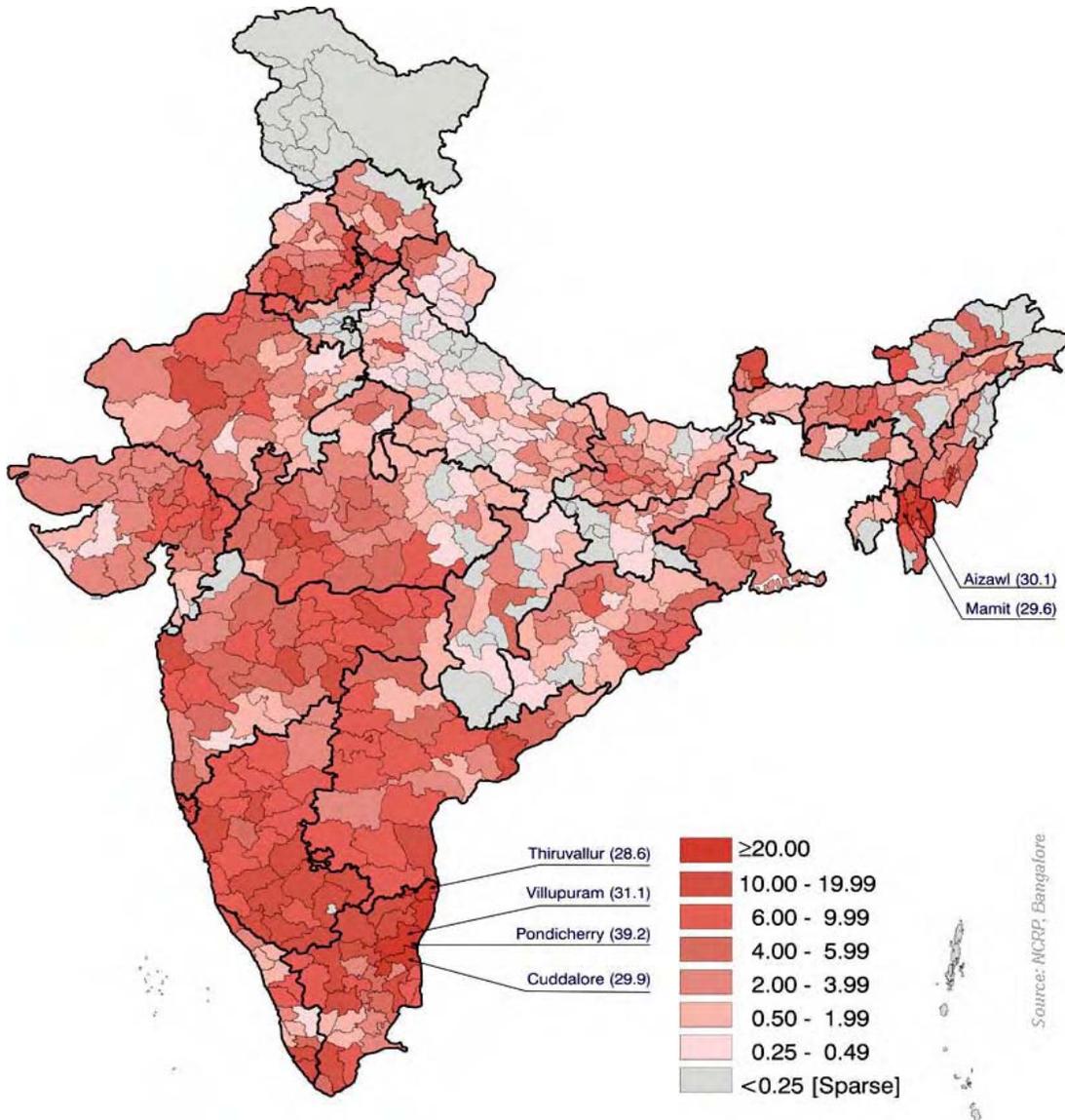


Figure 1: Minimum age adjusted Incidence Rates of Cervical Cancer per 100,000 females by district.

One out of every five women in the world suffering from this disease belongs to India. More than three-fourths of these patients are diagnosed at advanced stages leading to poor prospects of long-term survival and cure. It is estimated that there were 112,609 new Cervical Cancers in 2004 and this number is expected to rise to 139,864 in 2015 (Burden of Disease in India. Background papers. National Commission on Macroeconomics and Health. September 2005). The occurrence of Cervical Cancer varies widely in India and Fig.1 shows the minimum age adjusted incidence rates of Cervical Cancer per 100,000 females by districts (Development of an Atlas of Cancer in India. Indian Council for Medical Research, 2004).

Cervical Cancer can be prevented by screening women systematically through organized population based programmes. Screening aims to detect the disease at the precancer stage when it is amenable to simple treatment and cure. In many of the developed countries the annual incidence and mortality from this cancer have gone down by 50-70% since the introduction of population based screening.

In India, despite the public health importance that cervical cancer merits, there are only sporadic efforts in hospitals and research settings.

Regular population based screening using Pap smear cytology is the internationally accepted screening method for cervical cancer. The health infrastructure and organizational aspects for a such a screening programme based purely on the Pap smear are not available in India at present. However, the magnitude of the problem of cervical cancer, and the potential for prevention, makes it imperative to identify a feasible strategy in the Indian settings. Various studies in India and in other countries have demonstrated the usefulness of alternative strategies such as 'visual inspection with acetic acid' for categorising women as 'high risk' and 'low risk' (Accuracy of visual screening for cervical neoplasia: results from an IARC multicentre study in India and Africa. *International Journal of Cancer*. 2004, 110: 907-913).

An Expert Committee Meeting was held on 18-19th November 2005 in the Department of Cytology and Gynecologic Pathology, Postgraduate Institute of Medical Education and Research, Chandigarh to develop guidelines for undertaking Cervical Cancer Screening through the existing health system.

Experts were drawn from all the relevant specialities and from all the levels of health care. The list of the participants is provided in Annexure 1.

II. OBJECTIVES OF THE EXPERT GROUP MEETING

1. To identify a **feasible strategy** to initiate population based cervical screening programme in India in **pilot settings**.

2. To identify **appropriate screening test/tests** and the diagnostic and therapeutic algorithms for follow-up.

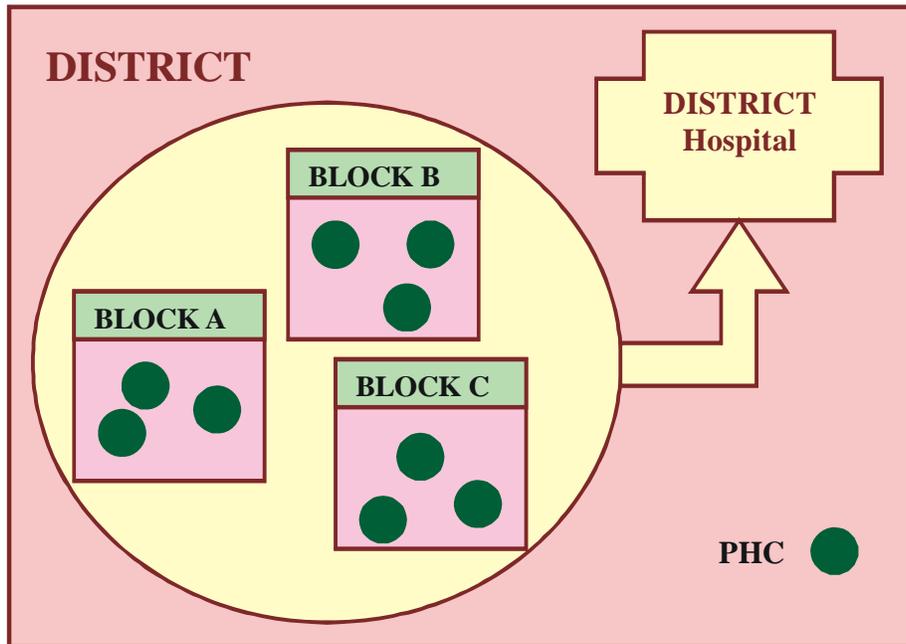
3. To suggest feasible mechanisms for conducting such a programme within a **district** with appropriate **linkages**.

III. IMPLEMENTATION OF CERVICAL CANCER SCREENING PROGRAM (CCSP)

There are various limitations in undertaking organized population based Cervical Cancer Screening Programmes in India. The resources and infrastructure vary widely in different parts of the country and within states. Pap smear based cervical screening has reduced Cervical Cancer incidence and mortality in different parts of the world. If facilities and resources are available such options can be undertaken. However, for the large population of India the infrastructure and resources do not permit Pap smear based screening programmes except in a few settings. Hence an alternative strategy has to be identified, which is scientifically correct, ethical and feasible. The following guidelines pertain to areas which do not have the capacity for undertaking Pap smear based cervical screening programmes for large populations.

It is proposed that the Cervical Cancer Screening Programme should be started as demonstration programmes in settings that can take up the load of screening women in large numbers. The proposed strategy plans to cover women in the age group of 30-59 years using primarily the alternative screening tests starting at the Primary Health Centres. The District Cancer Control Programme under the National Cancer Control Programme is a good avenue to pilot this screening strategy. The unit of operation will be the District and for the demonstration program, 3 blocks in the District can be identified (Figure 2). One block is likely to have 4 to 5 PHCs and a total population of 100,000. Box 1 provides the calculation for the number of eligible women.

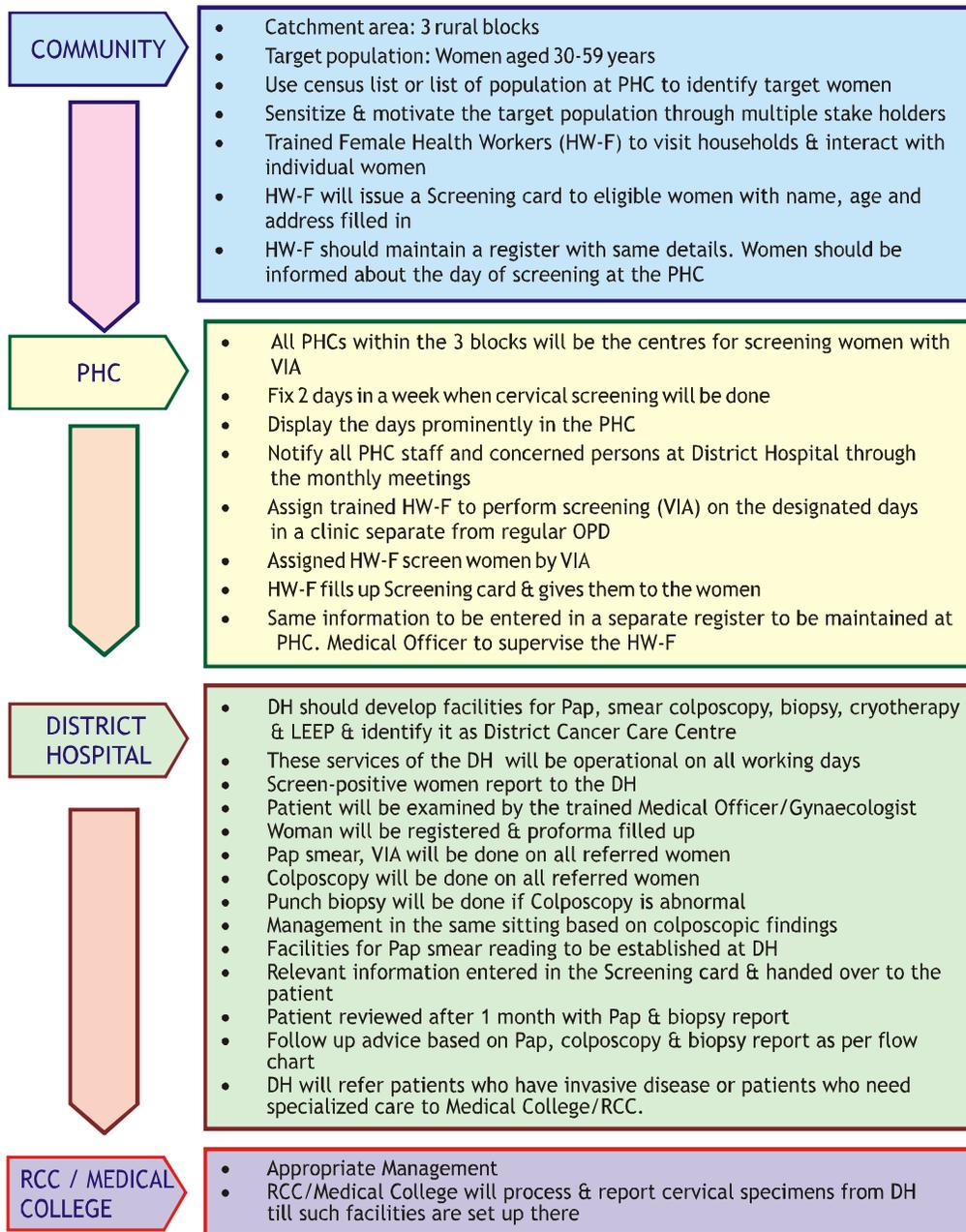
Figure 2: A model demonstration programme for implementation of CCSP



Box 1. Calculation of the number of eligible women in a PHC

1. Identify the size of the population under the PHC
 Example: = 30,000
2. Calculate the number of women in this area
 Example: 50% of population = 15,000
3. Estimate the number of women in the target age group (30-59 years) to be screened
 Example: 30% of all women = 4,500
4. Calculate the total number of women to be screened
 Example: the programme goal is to screen 80% of women aged 30-59 years = 3600

Suggested scheme at various levels for a Population based Screening Programme for Cervical Cancer



The programme has to be undertaken after extensive consultations with the various stakeholders and by involving them in the strategic planning. The District administration and nearby Medical College/ Regional Cancer Centre have to be sensitized and they have to agree to participate actively in the programme, deal with the referrals and act as technical support. It is important to map the resources and referral pathways and identify agencies/officers with specific responsibility.

The proposed plan is to screen women using Visual Inspection after Application of Acetic Acid (VIA) at the PHC and then a single-visit approach for further investigation and management at the District Hospital. The management at the District Hospital is planned in such a way that treatment based on Colposcopy is offered in the same visit. Pap smear and Biopsy are investigations that are done to ensure that there is cytological and histopathological back-up for the intervention. *If the woman is sent home after a Pap smear, it is likely that a large proportion of women will not turn up to collect the results and hence the effectiveness of the screening programme will not be achieved.*

After implementation of the population based programme, the process has to be monitored and reviewed closely. Appropriate changes should be made as we gain experience in organizing population based screening programmes and as the capacity of the health system increases in terms of personnel and infrastructure.

A. Community sensitization & motivation

Intensive information, education and communication (IEC) activities are required to sensitize the community about the significance of the disease and its early detection through screening. Detailed discussion on the IEC strategies is beyond the scope of the current document. Briefly, the recommendations are:

- Simple and appropriate health messages have to be disseminated in the local language taking into consideration the local culture and traditions.

- Health workers should be trained and provided with IEC materials so that they can interact one-to-one and motivate the target women.
- Both print and electronic media have to be utilized and other local modes of communication like folk arts should be used appropriately.
- All efforts should be made to gain cooperation from the community for these IEC activities. Rural administrative heads, political leaders, religious leaders and other peer groups should be sensitized and their help should be sought to motivate the target population.
- Anganwadi workers, voluntary health groups, NGOs etc wherever present should be contacted for their cooperation in these activities
- Along with the messages related to cervical screening, women should also be made aware of a healthy lifestyle, hygienic practices, early symptoms of common cancers, importance of early detection, prompt treatment, and follow-up.

B. Organization of CCSP at the Primary Health Centre

1. Role of various functionaries

Each PHC has to take up the responsibility of screening women who reside in its catchment area.

The Medical Officer of the PHC will be responsible for implementing the Cervical Cancer Screening programme at the PHC. Each PHC has a Public Health Nurse and Health Assistants (male and female) who assist the medical officer in supervising the work of the Health Workers. The backbone of the health system is the cadre of health workers, both male and female. They are also known as multi-purpose workers. The health workers pay home visits, maintain the family records and provide promotive and preventive services. The Medical Officer, Public Health Nurse, Health Assistant (female), and Health Workers (female) will have to take a lead in the screening programme.

2. Screening

a. Training of personnel

Training and periodic re-training are most important determinants of good performance of VIA by the screen providers (health workers, nurses, health assistants or medical officers). After initial training, reorientation training should be done after 6 months and then yearly. If some provider is found to be missing the abnormalities frequently or is having too high or too low a test positivity, she should be re-trained by the medical officer.

Preparation for screening

- An estimate of the total number of women in the target age group of 30 to 59 years living in the coverage area can be obtained from the district census data or from the list of families available at the PHC.
- According to convenience of the PHC, two days in a week should be designated for Cervical Screening.
- The days for Screening should be prominently displayed through billboards near the PHC. The days should be announced at the monthly meeting of the PHC and also of the District Hospital so that the information is widely circulated.
- Essential supplies for screening like instruments, consumables, forms etc are to be arranged (Box.2). The protocol of disinfection and sterilization of different instruments should be followed meticulously.
- The multipurpose health workers should make home visits to inform women about the cervical screening facility and try to motivate them to attend the PHC on any of the designated days. Each eligible woman has to be handed over a Screening Card with the name, age and address filled up (Annexure 2). The health worker will have to record the same information in his/her register.

Box 2. Supplies and equipment required for VIA at the PHC

1. Examination gloves (sterile or non sterile)
2. Examination table
3. Vaginal Speculum (preferably Cusco's or Sim's)
4. Cotton tipped swabs
5. Freshly prepared 5% acetic acid
6. Focusing light (with halogen bulb preferred)/torch/flashlight
7. Rubber/plastic sheets
8. Small bowl for acetic acid
9. A screen or separate room or space with privacy
10. VIA forms
11. Registers

Screening procedures

- If possible, screening should be done in a room separate from the regular OPD.
- About 30-50 women can be screened in a day.
- Screening should primarily be performed by trained Health Workers (female).
- Screening should be done using the Visual Inspection after Application of Acetic Acid (VIA) test. Freshly prepared 5 % acetic acid (Box 3) should be used for the test.
- The Health Worker will record the VIA findings on the Screening Card and hand it over to the woman. The findings should also be recorded in the register that is to be maintained in the PHC.

Box 3. Preparation of 5% acetic acid**Ingredients**

1. Glacial acetic acid	5 ml
2. Distilled water	95 ml

Preparation : Carefully add 5 ml of glacial acetic acid into 95 ml of distilled water and mix thoroughly

Storage : Unused acetic acid should be discarded at the end of the day

Label : 5% dilute acetic acid

Caution : It is important to dilute the glacial acetic acid since the undiluted acid causes severe chemical burn, if applied to the epithelium

Conveying the result and further referral

- If a woman is found positive she should be referred to the District Hospital. She should be explained the implication of the positive test and the importance of further investigations. She should be properly guided to attend the District Hospital.
- If VIA test is negative the woman should be explained the implication of the result, reassured and advised to come for repeat screening after 5 years. The woman should report to the PHC if she develops any symptoms.

3. Monitoring and evaluation

The Medical Officer (MO) will have to supervise the activities of the health workers, ensure proper maintenance of records, generate monthly activity reports and implement the quality control measures as per the following guidelines.

Each newly trained nurse/health worker should do at least 100 visual tests under direct supervision of the MO. Once they achieve reasonable degree of confidence, the MO will cross check all the positive cases and 10% of the negatives reported by the health workers. The MO has to ensure that proper disinfection and sterilization techniques are being followed.

Record keeping and maintenance

The MO will ensure that the all the relevant fields of the screening card are filled up after screening and the card is handed over to the woman. The M.O. will see to it that a register for all screened women, recording the details of the women and the VIA results, are maintained by the PHC. The procedures and the outcome of the interventions at the District hospital should be informed to the referring PHC and the PHC should keep a note of these. A report is to be sent to the District hospital in the prescribed format (Box 4) for uniformity.

<i>Box. 4. Format for reporting from PHC to District Hospital</i>			
Age group	Number screened (A)	Number positive (B)	Positivity rate (B/A)%
<30 years*			
30-39 years			
40-49 years			
50-59 years			
> 60 years*			
Total			

* Women who were screened outside the target age group of 30-59 years

The progress of work related to cervical screening should be reviewed along with the other activities during the monthly meetings of the PHC, using the parameters given in Box 5.

<i>Box 5. Monitoring Indicators in a PHC</i>	
Month_____	PHC_____
1. Number of women contacted (A)	
2. Number attended for VIA (B)	
3. Number of women with positive test result (C)	
4. Test positivity rate (C/B) %	

On an average 30-50 women can be screened on each screening day. The expected VIA positivity is about 10-15%. The newly trained screen providers are likely to have higher test positivity in the beginning. With experience and retraining the test positivity comes down. Any problems faced by the workers or the women in relation to the screening programme should be brought to the notice of the MO and discussed in the monthly meetings. Prompt response to any problem in the community is important in order to ensure adequate compliance of the target population.

C. Organization of Cervical Cancer Screening Programme at the District Hospital (DH)

The district hospitals have to be equipped as the referral centres for investigations and management of the women who will be referred from the Primary Health Centres. Other related activities will include training of the medical personnel, coordination between various stakeholders and monitoring the entire programme of the District. (Under the District Cancer Control Program it has been proposed to set up a Cancer Detection Centre (CDC) in each district hospital (DH) and if organized this will be a good mechanism for taking up cervical cancer screening). All women referred from PHCs for further investigation, treatment or follow up will report to DH.

1. Role of various functionaries

The nodal officer (who can be the Reproductive and Child Health Officer / Gynaecologist / Superintendent of the district) will be responsible for implementing the Cervical Cancer Screening Programme (CCSP) His/her responsibilities in the implementation of CCSP at the district level will be as follows:

- As the program manager he/she will assess the existing facilities in the district hospital and depending on the need will develop the infrastructure and procure necessary equipment and consumables.
- He/she will set up the logistics so that the screen-positive women referred from primary health centres are registered at the DH and can undergo the necessary investigations and treatment with a minimum number of visits, preferably through a 'single window' system. The requirements for the CCSP at the DH are listed in Box 6 (Page 19) and Box 7 (Page 20).
- He/she will identify the medical and supporting staff who will be involved in doing Colposcopy and treatment and will arrange for their training at the designated centre.
- He/she will have to organize periodic training programmes at the DH for the medical personnel and supporting staff involved in cervical screening at the primary levels.
- He/she will collect inputs from the primary health centres as well as from the DH, analyze them and monitor the progress of the programme in the district.
- The quality control indicators listed in Box 8 (Page 21) can be followed for monitoring the programme.

The trained doctors assigned by the nodal officer of the DH can be responsible for the patient management. His/her responsibilities in the implementation of the Cervical Cancer Screening Programme in the district will be as follows:

- Perform Colposcopy, biopsy and cryotherapy as required (If properly trained can do LEEP).
- Will be involved in the IEC activities and counseling of the patients who need Colposcopy &/or treatment.
- Will supervise the day to day activities and will generate the monthly reports.

Trained district hospital staff nurses may be deputed for the CCSP. Their responsibilities will be to assist the medical officer in screening, Colposcopy & treatment. She will also help the medical officer maintain the records.

2. Protocol for Further Evaluation & Treatment of Screen-positive Women

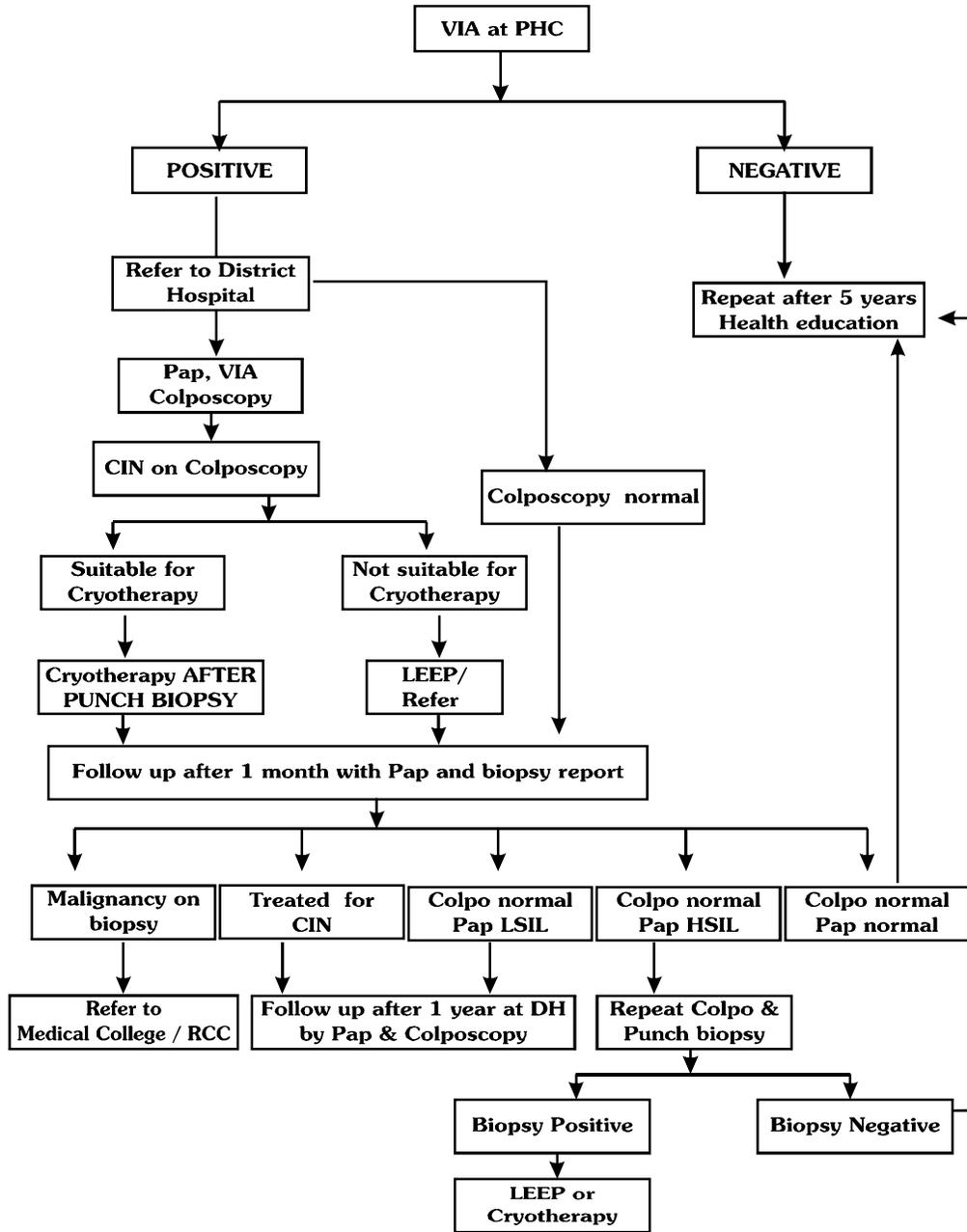
- A Colposcopy clinic has to be set up at the DH, where women referred from the primary health centres who are positive for VIA, will have a repeat VIA, Pap smear, Colposcopy and Punch biopsy (based on the Colposcopy finding) on an out-patients basis. The clinic should be operational on all working days.
- Referred women should be registered and a PHC-wise Screening register should be maintained. Women can also attend the DH clinic directly (without being referred from the PHC) and they should also be provided the facility and listed separately.
- Each woman has to be examined by a trained Medical Officer who will first obtain a Pap smear and then repeat VIA.
- All women should have Colposcopy irrespective of VIA findings.
- Punch biopsy should be obtained if there is any abnormality on Colposcopy (unless the patient is treated by LEEP at the same sitting).
- After an informed consent, patient will be treated as per the Colposcopic findings.
- Cryotherapy is the treatment of choice for the ecto-cervical lesion that occupies less than three fourths of transformation zone and can be covered by cryo-probe. Obtaining a punch biopsy is mandatory prior to cryotherapy.

- Lesions not suitable for treatment by cryotherapy should be treated by Loop Electrosurgical Excision Procedure (LEEP) and the specimen has to be subjected to histopathology. (If this facility is not available, then the patient should be referred to the nearby Medical College/RCC)
- The results of VIA and Colposcopy and information regarding treatment have to be entered in the Screening register and also in the Screening card being carried by the patient.
- Pap smear and histology requisition forms and informed consent forms for treatment have to be filled up as required.

Conveying the results and follow up

- All women should be advised to return after one month.
- All the treated women should be reviewed with the histopathology report (of punch biopsy or LEEP specimen) at one month follow up visit. They should be clinically examined for any evidence of complication. No screening test or Colposcopy should be done at the one month follow up visit.
- All treated women whose histology does not have any evidence of invasive disease should be advised to attend DH after one year, when repeat Pap smear and Colposcopy should be done.
- If there is evidence of invasive disease in any of the biopsy specimens the woman should be referred to the tertiary center (RCC / Medical College)
- All women who have not undergone any form of treatment (Colposcopy normal and no biopsy done) in the initial visit should be reviewed with their Pap smear report.
- If the Pap smear report is HSIL or worse, Colposcopy should be repeated. If Colposcopy is still normal, the Pap smear may be reviewed by the Pathologist. Alternatively, punch biopsy may be taken from the anterior and posterior lips of apparently normal cervix. If biopsy report is normal the woman should be recalled after one year for repeat Colposcopy at DH.

The following scheme depicts the protocol of management and follow-up of the screen positive women at the district hospital.



- If Pap smear shows low grade abnormality and the initial Colposcopy was normal the woman should be advised repeat screening after 1 year at DH
- If the Pap smear shows NO epithelial abnormality, the woman may be advised re-screening after 5 years at the PHC.
- Unsatisfactory Colposcopy along with HSIL on cytology is an indication for LEEP
- Primary screening facilities should also be set up at the district hospitals following the same guidelines as that for PHCs for the women staying around the district hospital and for the women attending the hospital for various other reasons. The staff nurse should be trained to carry out screening by VIA at DH.

Box 6. Requirements for Colposcopy and Cryotherapy at District Hospital

- Existing gynecology OPD can be reorganized to start Colposcopy services
- Gynecologic examination table
- Focusing light preferably halogen lamp
- Ayre's spatula & cytobrush
- Glass slides, coplin's jar & 95% ethyl alcohol
- Colposcope
- Cusco's specula of different sizes
- Cervical punch biopsy forceps
- Endocervical forceps or long straight artery forceps
- Examination gloves
- Cotton-tipped swabs
- 3-5% freshly prepared acetic acid
- Formaldehyde solution
- Silver nitrate crystals
- Cryotherapy equipment
- Carbon dioxide or Nitrous oxide cylinder
- Sterilizer

Box 7. Requirements for LEEP at District Hospital

- An operation room or any room designated for minor surgical procedures
- Electrosurgical unit (ESU)
- Loop diathermy electrodes (at least 8 mm radius) that fit into the ESU
- Ball or needle diathermy electrodes
- Suction machine (smoke evacuator preferred)
- 2% lignocaine (with and without adrenaline)
- A 26 G spinal needle is most suitable for infiltrating the cervix with lignocaine
- Facilities for general anesthesia
- Colposcope & other consumables required for Colposcopy

3. Monitoring and evaluation at the DH

Supervision

The Nodal Officer of the DH will supervise the routine work of the Colposcopy clinic and the cytopathology laboratory.

Record Keeping and Data Management

Besides maintaining the hard copies of the records in the forms and the registers, the DHs should be equipped with computerized system of data storage. The ScreenReg software programme of the International Agency for Research on Cancer can be adapted to the local need and a dedicated data entry operator is essential. It is mandatory to keep all the slides for a minimum period of 5 years.

Monitoring of monthly activities and Internal Quality Control

All activities carried out at the DH should be monitored monthly according to the indicators (Box 8). The monthly report from the PHCs should also be reviewed and action taken whenever necessary.

Box 8. Monitoring Indicators in District Hospitals

MONTH _____

DISTRICT _____

1. Number of women referred from PHCs (number of women with positive screening test to be collected from PHCs) (A)
2. Number of referred women registered at DH (B)
3. Compliance to referral (B/A)
4. Number of women who had Colposcopy (C)
5. Compliance to Colposcopy (C/A)
6. Number of cases in which suspicious lesions were found on Colposcopy (D)
7. Number of women who had biopsy (E)
8. Proportion of colposcopically abnormal women who had biopsy (E/D)
9. Number of women detected to have CIN on biopsy (F)
10. Number of women with CIN who received treatment (G)
11. Compliance to treatment (G/F)
12. Proportion of women referred for positive screening tests who had abnormality on Colposcopy (D/C)
13. Proportion of women referred for positive screening tests who had CIN on histology &/or Colposcopy $[F + (D-E) / C]$
14. Number of women referred to tertiary centres for invasive cancers & their treatment status

Ensuring quality performance of Colposcopy and Treatment

The DCCP Nodal Officer will be responsible for internal QC exercise. The colposcopists must be trained at the School for Cervical Cancer Prevention or at an appropriate training Centre before initiating Colposcopy and treatment. Periodic review of the biopsy reports and correlating them with the Colposcopy findings can give an idea about the accuracy of Colposcopy. Maintenance of the equipments in proper shape and ensuring ready supply of essential consumables are also important for quality performance.

IV. ESTABLISHMENT OF CYTOLOGY SERVICES AT THE DISTRICT HOSPITAL

This section will focus on issues related to the provision of Cytology Services in the existing Pathology Laboratory in a District Hospital. As part of the strategy for a CCSP for India, there is a need to provide Pap smear screening facility at the District Hospital and to upscale existing facilities at all tertiary care centers. (The number of Pap smears expected can be worked out as given in Box. 9). This will involve careful and systematic planning starting from collection of the smears, their transportation, smear screening, reporting and ensuring the delivery of the report to the medical officer who will take an appropriate action (management). The list of materials required to set up cytology services is provided in Box 10.

Box 9. Estimation of the number of cervical Pap smears

1. Identify the number of PHCs under the District Hospital.
2. Each PHC is assumed to cater to a population of 30,000. Hence approximately 3600 women will be screened at the primary level using VIA.
3. Assume that at least 15% will be positive by the primary screening test. That means expect 500 women who will *require* Pap smear services per PHC.
4. Multiply the number of PHCs X500 to get an estimate of the number of Pap smears to be expected.

Box 10. Materials required for Cytology Laboratory to perform Pap smears

Non-Consumables

Coplin jars with lids: 20

Diamond pencil (for numbering slides) / ordinary lead pencil (if frosted glass slides can be provided): 2

Slide Trays (aluminium): 6

Glass jars [dimensions : 11 X 9 X16 cms approx, or 10 X 9 X 6 cms approx]: 30

Staining racks (made of aluminium or steel and can carry 16 slides): 6

Slide cabinets or Storage racks (for storing stained slides): 1 (having capacity of 10,000 slides; 100 slides per rack)

Consumables (for 1000 Pap smears)

Gloves: 12 pairs

Glass slides: 1000

Cover Slips [40mmX 24mm] - 1000

Slide Labels: 1000

Register : 2 per year

Chemicals

Alcohol, absolute: 12 L

Hematoxyline, Harris - 5g

Mercuric oxide - 2.5 g

Potash Alum (Aluminium Ammonium Sulphate) - 500g

HCl - 250 ml

Lithium Carbonate - 100g

OG6 - 20g

EA (modified)

Eosin, spirit soluble - 10g

Light green- 4g

Xylene - 2L

DPX (mountant) - 250 ml X 2

1. Role of various functionaries

The Chief of the Cytology Services will be the Pathologist with training and experience in cytology. It is proposed that all the pathologists posted in the District Hospital undergo training at any tertiary centre for a period of 3 months to obtain orientation and capability to report cervical smears.

In anticipation of the proposed workload, it is proposed to create the post of cytotechnologist/ cytoscreener who will be responsible for managing the Cytology Service Laboratory. Cytoscreeners are those who are specially trained to screen Pap smears. The minimum qualification will be B.Sc + 2 years training in any referral centre. The Cytotechnologists who have passed the Indian Academy of Cytologists Certification Exam can be considered for this position.

He/ She will have to ensure the smooth functioning of the laboratory starting from specimen reception to the generation of the report. He/She will also ensure that Internal Quality Control measures are undertaken.

The Laboratory technician posted in the District Hospital Laboratory will undergo training for a period of 1 month in a Cytology Laboratory in a tertiary referral centre and be certified to carry out the staining of Pap smears, as a Cytotechnician.

2. Pap smear

- **Smear takers:** Smears may be taken by the Multipurpose Health worker, Nurse or the Medical Officer.
- **Training and certification:** All paramedical staff will undergo training in taking of Pap smears for at least a week.
- **Procedure:** The subject will lie on the examination table. Smears will be taken using an Ayre's Spatula (disposable, wooden). After visualizing the cervix using the Cusco's speculum, the spatula will be inserted into the cervical canal, and by a rotary motion will sample the transformation zone. The material will be immediately spread onto numbered glass slides. These will be immediately fixed in 95% alcohol.

- **Laboratory Form:** This will contain fields of patient identification number, age of patient, date of last menstrual period and result of the VIA test (Annexure 3).

Laboratory Procedure

The technician will receive the slides and the duly filled forms in the Cytology Laboratory. He/She will enter the patient identification particulars into a Register and on to the computerized database. The Papanicolaou staining will be performed on the smears.

Pap Smear Reporting

It is essential to provide good quality binocular microscopes for the purposes of screening Pap smears. Marking pens are also required to mark the area showing atypical cells. The cytotechnologist will carry out the initial screening. The Cytotechnologist can sign out all cases, which are negative for epithelial abnormalities. Only the Pathologist will report any epithelial abnormality.

Reporting Format

It is recommended that the Bethesda System of Cervical Pap smear reporting (2001) as applicable to conventional smears be followed (Annexure 4).

3. Quality control

The Laboratory Chief pathologist will implement the Quality Control measures. At least 10% of all slides reported negative by the Cytoscreener / Cytotechnologist must be rescreened by the pathologist. Cytologic findings should be periodically correlated with the subsequent histopathology results.

4. Histopathologic evaluation of Cervical Biopsy / LEEP specimen

It is recommended that the cervical biopsy and LEEP specimen be subjected to histopathological processing at the linked up tertiary care centre (Annexure 5).

This will involve transportation of the specimen in 10% buffered formalin. The sections may then be transferred to the Pathologist at the District Hospital for reporting. It is preferable that at least one more pathologist also reports (Annexure 6) on the biopsy section at the linked-up tertiary care center.

V. HUMAN RESOURCE DEVELOPMENT AND CAPACITY BUILDING

Each state should have at least one designated training centre. The already existing centres for training and capacity building at Trivandrum (RCC), Chennai (RCC), Ambillikai (Christian Fellowship Community Health Centre, Bangalore (RCC), Hyderabad (RCC), Mumbai (RCC), Kolkata (RCC), Barshi (Nargis Dutt Memorial Cancer Center), New Delhi (AIIMS), Jaipur (RCC) and Chandigarh (PGI) should be recognized as Schools for Cervical Cancer Prevention (SCCPs) and new resource centers should be identified to cater to the remaining states. A new training center may be established in East India, possibly in Assam, with assistance from the International Agency for Research on Cancer (IARC).

There should be separate structured course modules for Programme managers (DCCP Nodal Officers, CMOHs), Clinicians (DH Medical Officers, Medical officers & Gynecologists of district hospitals, Medical Officers of PHCs), and paramedical staff (Nurses, Health Workers and Health Assistants). The SCCPs will arrange periodic reorientation courses for Pathologists, Cytotechnologists and Cytotechnicians also. For logistic convenience the training of the staff attached to the PHCs will be done at the District Hospitals. The training at the DHs will be conducted by a resource person from SCCP, along with one of the clinicians of DH trained at SCCP to be the master trainer. The master trainer will be provided with the course curriculum, guidelines and the training materials by the SCCP. He/she should be utilized for the refresher courses subsequently to be held for the paramedical staff.

The course modules should be tailored to the need and the baseline level of knowledge and competence of the trainees. There will be didactic theoretical sessions but more stress will be on adequate hands on practical training.

The SCCPs can network among themselves to develop a uniform course curriculum and resource materials. The resource materials developed by International Agency for Research on Cancer (IARC) can be used by the SCCPs after translating and adapting them to the local needs, if required.

The duration of training may vary according to the course module. It is generally accepted that a minimum of 4 days training is required both for the clinicians and the paramedics to achieve a reasonable degree of competence. During the course period they should be exposed to adequate number of procedures. There should be pre-course and post-course evaluations. In the post-course evaluation the trainees have to perform upto a pre-set standard (eg. answer at least 80% of the questions correctly) to be eligible to be inducted in the programme. At the successful completion of the course each trainee should be issued a certificate by the SCCP. Even after completion of training, the paramedics should perform at least 100 VIA tests under the supervision of a trained doctor before she is allowed to do the procedures independently.

The personnel required for the entire programme starting from the PHC to the tertiary referral centre is depicted in Box 11 as the Human Resource Matrix. Their involvement in each of the activities of the screening process to make the Cervical Cancer Screening Programme successful is also indicated .

Box 11. Human Resource Matrix*+ Sensitization, ++ Minimal, +++ Intensive*

Category	IEC	VIA	Pap Smear	Cytology	Colpo- scopy	Cryo therapy	Organizational aspects
Health worker	+++	+++	-	-	-	-	+
HI/PHN	+++	+++	-	-	-	-	+++
PHC Medical Officer	+++	+++	+	-	-	-	+++
Cytotechnician/ Cytoscreener	+	++	+++	+++	+	-	++
Lab technician	+	++	+++	+++	+	-	++
DH Staff Nurse	+++	+++	+++	+++	+++	+	+++
DH Medical Officer	++	+++	+++	++	+++	+++	+++
Pathologist	-	+	+++	+++	+++	++	++
Trained	+	+++	+++	+++	+++	+++	++
Medical officer							
Nodal Officer (Dist RCH \ Officer / Gynaecologist)	+++	+++	+++	+++	+++	+++	+++
Med. Supdt of the hospital	+	+	+	+	+	+	+++

ANNEXURE 1. List of participants

1. Dr. Cherian Varghese, WHO India Country Office, New Delhi.
2. Dr. R. Sankaranarayanan, Representative of the International Agency for Research on Cancer, Lyon, France.
3. Dr. Usha Saraiya, Consultant, Cama and Albless Hospital Representative of the Federation of Obstetrics and Gynecological Societies of India.
4. Dr. RGW Pinto, Dept. of Pathology, Goa Medical College, Representative of the Indian Academy of Cytologists.
5. Dr. Kusum Verma, Dept. of Pathology, AIIMS, New Delhi.
6. Dr. Baridalyne Nongkynrih , Dept. of Community Medicine, AIIMS, New Delhi.
7. Dr. Partha Basu, Dept. of Gynecologic Oncology, CNCI, Kolkata.
8. Dr. D. Barmon, Dept. of Gynaecologic Oncology Representative of RCC, Guwahati.
9. Dr. Ramani S Wesley, Dept. of Community Medicine, RCC, Trivandrum.
10. Dr. K.R. Pillai, Cytotechnologist, RCC, Trivandrum.
11. Dr. S. Bhambhani, Cytopathologist, Institute of Cytology and Preventive Oncology, New Delhi.
12. Dr. S. Shastri, Head of Community Oncology, Tata Memorial Hospital, Mumbai.
13. Dr. R. Premkumari, Dept. of Community Medicine, WIA, Adyar, Chennai.
14. Dr. S.C. Sharma, Dept. of Radiotherapy, PGIMER and Officer in Charge, RCC, Chandigarh.
15. Dr. F. D. Patel, Dept. of Radiotherapy, PGIMER, Chandigarh.

16. Dr. Subhas K. Gupta, Dept. of Cytology, PGIMER, Chandigarh.
17. Dr. Sarala Gopalan, Dept. of Obstetrics and Gynecology, PGIMER, Chandigarh.
18. Dr. Lakhbir Dhaliwal, Dept. of Obstetrics and Gynecology, PGIMER, Chandigarh.
19. Dr. Vanita Suri, Dept. of Obstetrics and Gynecology, PGIMER, Chandigarh.
20. Dr. Arvind Rajwanshi, Dept. of Cytology and Gynecologic Pathology, PGIMER, Chandigarh.
21. Dr. Raje Nijhawan, Dept. of Cytology and Gynecologic Pathology, PGIMER, Chandigarh.
22. Dr. Radhika Srinivasan, Dept of Cytology and Gynecologic Pathology, PGIMER, Chandigarh.
23. Dr. A. Huria, Dept. of Obstetrics and Gynecology, Govt. Medical College, Chandigarh.
24. Dr. J. S. Thakur, Dept. of Community Medicine, PGIMER, Chandigarh.
25. Ms. Paramjit Kaur, Public Health Nurse, PGIMER, Chandigarh.
26. Ms. Tsering Dolkar, Nursing Sister, PGIMER, Chandigarh.
27. Ms. Sunita Sharma, ANM, PGIMER, Chandigarh.
28. Ms. Shakuntla Mehra, ANS, PGIMER, Chandigarh.

ANNEXURE 2: CERVICAL CANCER SCREENING CARD
(To be filled at the PHC)

State: _____

Name: _____ Age: _____

ID No
 District PHC Year Registration no

Address: _____

VIA done on: ____/____/____ (DD/MM/YYYY)

VIA result :

- Negative Positive Positive Invasive Cancer

Done by: _____

(To be filled at the District hospital)

LMP: ____/____/____ (DD/MM/YYYY) Parity: _____

Complaints:

- None Vaginal Discharge Irregular bleeding Post Coital bleeding
 Menorrhagia Post menopausal bleeding others (specify)

Contraception:

- None Barrier Hormonal IUCD Tubal Others

Tests and procedures done at DH

Date	Procedure	Result	Remarks
	VIA		
	PAP		
	COLPOSCOPY		
	PUNCH Biopsy		

Treatment :

- Not required Cryotherapy Leep Others (specify)

Advice: _____

Signature _____

ANNEXURE 3: CERVICAL PAP SMEAR REQUEST FORM

SLIDE NO: _____ New Follow up

Name : _____ Age: _____

ID No
District PHC Year Registration no

Address: _____

Pap done on: _____/_____/_____ (DD/MM/YYYY)

LMP: _____/_____/_____ (DD/MM/YYYY) Parity: _____

Complaints:

- None Vaginal Discharge Irregular bleeding Post Coital bleeding
 Menorrhagia Post menopausal bleeding others (specify)

Contraception:

- None Barrier Hormonal IUCD Tubal Others

Per Speculum Findings:

- Cervix noraml Erosion Bleeds on touch Suspicious

Colposcopic Findings:

- Not done Normal Immature metaplasia
 HPV Low grade lesion High grade lesion
 Invasive Caricimoma Unsatisfactory Others (Specify)

Date

Signature

ANNEXURE 4: CERVICAL PAP SMEAR REPORT

SLIDE NO: _____ New Follow up

Name : _____ Age: _____

ID No

District PHC Year Registration no

Address: _____

Pap done on: ____/____/____ (DD/MM/YYYY)

- Satisfactory for evaluation Unsatisfactory (State reason)
- No evidence of epithelial abnormality Epithelial abnormality present

Infection : TV. / Candida / Coccobacilli / HSV / others

Atrophy

Repair

Radiation

IUCD effect

- Epithelial abnormality**

Squamous cells:

- ASC-US
- ASC-HSIL cannot be excluded
- LSIL (with or without HPV associated changes)
- HSIL CIN2 / CIN3
- Squamous cell carcinoma - ? Invasive / invasive

Glandular cells

- Endometrial cells, cytologically benign in post-menopausal woman
- AGUS
- Adenocarcinoma : endocervical / endometrial / others

CYTODIAGNOSIS:

RECOMMENDATION:

Date: Cytoscreener Cytopathologist

ANNEXURE 5: HISTOPATHOLOGY REQUEST FORM

(To be Filled in by the Medical Officer)

Specimen of: Cervical Punch/ LEEP/ Knife cone LAB No. _____

Name : _____ Age: _____

ID No
 District PHC Year Registration no

Address: _____

Collected on: _____/_____/_____ (DD/MM/YYYY)

LMP: _____/_____/_____ (DD/MM/YYYY)

Parity:

Complaints:

- None Vaginal Discharge Irregular bleeding Post Coital bleeding
 Menorrhagia Post menopausal bleeding others (specify)

Contraception:

- None Barrier Hormonal IUCD Tubal Others

Per Speculum Findings:

- Cervix normal Erosion Bleeds on touch Suspicious

Colposcopic Findings:

- Not done Normal Immature metaplasia
 HPV Low grade lesion High grade lesion Invasive Ca
 Unsatisfactory Others (Specify)

Date

Signature

ANNEXURE 6: REPORTING FORMAT FOR CERVICAL HISTOPATHOLOGY EXAMINATION

LAB HPE NO.

Name : _____ Age: _____

ID No

--	--

District

--	--

PHC

--	--

Year

--	--	--	--

Registration no

Address: _____

Referred by :

GROSS:

SPECIMEN:

- Biopsy Leep Cone Others

Biopsy :

No. of fragments and size

LEEP / CONE:

Dimensions

Resection margins.

Number of sections studied:

MICROSCOPY : Description

DIAGNOSIS (Select one or more as appropriate) :

- No epithelial abnormality

Chronic Cervicitis

Squamous metaplasia

- Epithelial Abnormality

CIN 1

CIN2

CIN3

Microinvasive Carcinoma

Invasive Squamous Cell Carcinoma

Adenocarcinoma - in-situ / Invasive

Note : If a biopsy shows more than one abnormality in foci, then the final diagnosis will be the highest degree of abnormality.

Date

Signature