



Operational Framework

Management of Common Cancers





Operational Framework

Management of Common Cancers

Ministry of Health and Family Welfare Government of India



जगत प्रकाश लड्डा Jagat Prakash Nadda



स्वास्थ्य एवं परिवार कल्याण मंत्री भारत सरकार Minister of Health & Family Welfare Government of India







I am happy that my ministry has developed an operational framework for screening and management of common cancer. On June 22nd this year. I had released guidelines for prevention, control and population level screening of diabetes, hypertension and common cancer. This framework provides mechanisms to operationalise screening and management of common cancer at field level. The framework fulfils the need of complex requirements for screening and management of common cancer viz. breast, oral and cervical cancer.

- 2. Early detection of cancer can lead to better health outcomes. This initiative of implementing population level screening for common cancer can save many precious lives and improve quality of life of many more. Population level screening envisages screening for risk factors, which will generate awareness on healthy living, thereby focussing on prevention of the diseases. Cancer share common risk factors with several other common Non-Communicable Diseases, such as diabetes and heart diseases. Therefore, preventive efforts shall address other Non-Communicable Diseases as well.
- 3. Our ambition to deliver high quality health care is to be matched by an equal commitment to deliver on the ground. Support to frontline workers and primary health care providers and strengthening of our secondary care services are necessary to provide early detection and follow-up services.

4. I urge States to take up the issue of cancer prevention, screening and treatment as a crusade and to use this framework to create the mechanisms needed to provide effective screening, care and treatment to all.

(Jagat Prakash Nadda)

348, ए-स्कंध, निर्माण भवन, नई दिल्ली-110011 348, A-Wing, Nirman Bhawan, New Delhi - 110011 Tele.: (O) +91-11-23061661, 23063513 Telefax : 23062358

E-mail: hfwminister@gov.in



सी.के. मिश्रा सचिव C.K. Mishra Secretary



भारत सरकार स्वास्थ्य एवं परिवार कल्याण विभाग स्वास्थ्य एवं परिवार कल्याण मंत्रालय Government of India Department of Health and Family Welfare Ministry of Health and Family Welfare



MESSAGE

Cancer has direct effects on individuals, their families and society as a whole. Premature deaths, the economic burden due to lost productivity and the costs associated with illness and therapy take a toll at the individual and population level.

This operational framework lays out the broad guidance for treatment of common cancers and is to implemented in continuum with and build on the recently issued screening guidelines for common non-communicable diseases.

We must consider how to most effectively use available resources in providing treatment for common cancers. Various social protection schemes of the State and the Centre will need to be synergized to address the costs of treating cancer.

There are other actions we need to take in addition to prevention and treatment. We must strengthen cancer registries and undertaking research in studying the burden and pattern of cancers, their impact on the poor, and strategies to address risk factors in different contexts and among sub populations.

Operationally States would need to adapt some of the delivery strategies, but the fundamental principles of access, affordability and university must underpin treatment for those with cancer.

Implementing a programme outlined in this operational framework, such as this signifies a change in the way our services are delivered. It will place stress on our health system, but with several new schemes that have just been announced, including for free drugs and diagnostics and strengthening district hospitals, and with the country moving forward on chronic disease care, I am confident that States will be able to meet this challenge.

(C. K. Mishra)

कमरा नं. 156, ए-स्कंध, निर्माण भवन, नई दिल्ली - 110011

Room No. 156, A-Wing, Nirman Bhawan, New Delhi - 110011

Tele: (O) 011-23061863, Fax: 011-23061252, E-mail: secyhfw@gmail.com

जीते जी रक्तदान, जाते-जाते अंगदान

Dr. Jagdish PrasadM.S. M.Ch., FIACS irector General of Health Services





भारत सरकार स्वास्थ्य एवं परिवार कल्याण मंत्रालय स्वास्थ्य सेवा महानिदेशालय निर्माण भवन, नई दिल्ली-110 108

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
DIRECTORATE GENERAL OF HEALTH SERVICES
NIRMAN BHAWAN, NEW DELHI-110 108
Tel: 23061063, 23061438 (O), 23061924 (F)
E-mail: dghs@nic.in

Dated: 26/08/2016

दिनांक / Dated.....

MESSAGE

Cancer is a growing public health problem concern in India. There are about 30 Lakh cases of cancer in India and about 13 lakhs occur every year. One-third of all cancers are preventable including tobacco use related cancers. Another one-third can be treated effectively if detected well in time. One third of cancer cases are seen in advanced stages and successful treatment may not be possible. Efforts from Govt, and community are required so that the cancer cases are detected and treated effectively in early stages.

In India, cancer control is a part of a comprehensive strategy for the prevention and control of non-communicable diseases that simultaneously promotes population-level health promotion and disease prevention and actively targets groups and individuals at high risk, while maximizing population coverage with effective treatment and care.

'Operational Framework: Screening and Management of Common Cancers' has been developed with series of meeting with experts and bearing in mind the feasible strategies in early detection of common cancers namely breast, cervical and oral cancers. States are expected to use the guidelines to build upon the implementation of NPCDCS while integrating into Health systems.

(Dr. Jagdish Prasad)



Arun Kumar Panda

Additional Secretary Tele: 23063155 Telefax: 23063156 E-mail: arun.panda@nic.in





निर्माण भवन. नई दिल्ली - 110011 Government of India Ministry of Health & Family Welfare Department of Health & Family Welfare Nirman Bhavan, New Delhi - 110011

23rd August, 2016

भारत सरकार रवास्थ्य एवं परिवार कल्याण मंत्रालय स्वास्थ्य एवं परिवार कल्याण विभाग



MESSAGE

A country such as ours, with the ongoing epidemiological and demographic transition and significant diversity, needs to consider not just how care can be delivered within the context of local health systems but also conform to the highest medical standards.

Therapeutic advances in chemotherapy, surgery and radiotherapy have helped in reducing cancer related mortality. But the disease necessitates long term follow-up, a critical component of care in chronic diseases and one with which our service providers, especially at primary and secondary care levels, are not yet familiar.

The recently launched operational guidelines for screening and prevention for common non-communicable diseases including cancer could be seen as a cornerstone of India's approach to cancer. This operational framework for management of common cancers builds on and is to be seen in continuum with the screening and prevention programmes.

We need to develop and mount a unique approach to dealing with cancer. The framework is one of a series of guidance documents for addressing non-communicable diseases. The focus on these three cancers is based on the fact that they are common, amenable to early detection and have a high potential for cure. However, it also lays the blueprint for a broad approach to treatment of other cancers.

The operational framework is just the beginning. States need to fill in the framework with local adaptions, create referral networks, and build partnerships with community and community based organizations not just for care but for support, rehabilitation and palliative care for cancer survivors and their families.



Under the umbrella of the National Health Mission, we have made progress in reducing disparities associated with access to care for maternal and child health services. We need to use those lessons to ensure that even as we initiate such treatment programmes, we are mindful of the fact that these disparities can be exacerbated in cancer diagnosis and treatment. We need to tailor strategies so that the poorest and the most vulnerable have equal access to cancer prevention, screening and treatment services.

(Arun K Panda)

AS&MD, National Health Mission



Manoj Jhalani Joint Secretary & CVO Telefax : 23063687

E-mail manoj jhalani@nic.in





भारत सरकार

स्वास्थ्य एवं परिवार कल्याण मंत्रालय निर्माण भवन, नई दिल्ली - 110011 Government of India Ministry of Health & Family Welfare Nirman Bhavan, New Delhi - 110011

FOREWORD

26th August 2016

The challenges to caring for cancer patients and cancer survivors are multiple and complex. The data from India reveal low cancer incidence rates but relatively high age specific death rates indicating that we need to strengthen early detection of cancers and appropriate and timely treatment.

This operational framework lays out broad programmatic guidelines and screening and management algorithms for three common forms of cancer- namely oral, breast and cervix that constitute a public health priority and should be understood and implemented in consonance with the Guidelines on Screening for Diabetes, hypertension and common cancers issued recently.

In the past decade, states have effectively used support from the National Health Mission to strengthen their health systems, supplementing and complementing state budgets. The rolling out of screening and treatment programmes for cancer will test the resilience of these systems and administrators and implementers alike will need to be mindful of the challenges this will pose.

Treatment for cancer is not to be seen as a vertical intervention. Under the National Health Mission, support is being provided for programmes such as the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke, the population based Screening programme for prevention, screening and control of non-communicable diseases (NPCDCS) and the National Programme for the Health-Care of the Elderly (NPHCE).

The approach that is highlighted in the framework which is distinct yet complementary to the programmes mentioned above is the emphasis on the primary and secondary health care services as the key points for screening and diagnosis for cancer.

While strengthening our tertiary level, regional cancer centres is important, innovations in treatment in a few states demonstrate that it is possible, with appropriate training and support to provide care for patients at the district hospital. The framework provides for strengthening district level histopathology facilities, and to create local hubs for timely diagnosis. States must consider innovative ways to partner with and collaborate with credible cancer care and support organizations.

Patients with cancer face multiple barriers. This framework is an attempt to address some barriers related to treatment, by clarifying levels of care at which confirmation of diagnosis, treatment and management need to take place.

Successful implementation of this framework rests with the state governments. We look to them to leverage and supplement existing resources in tandem with what the framework offers to provide timely, effective and quality treatment to those who seek care in the public health system, thereby building the community's confidence and trust in the system.

Finally, I would like to thank the technical experts who spared no effort, in ensuring that the protocols and algorithms articulated in this framework are consistent with existing evidence and appropriate for the context of health systems of our country.

(Manoj Jhalani)

LIST OF CONTRIBUTORS

- 1. Mr. C. K. Mishra, Secretary, Ministry of Health and Family Welfare
- 2. Dr. (Prof.) Jagdish Prasad, DG, Directorate General of Health Services
- 3. Dr. Arun K. Panda, Additional Secretary (Health), Ministry of Health and Family Welfare
- 4. Mr Manoj Jhalani, Joint Secretary (Policy), Ministry of Health and Family Welfare
- 5. Ms Limatula Yaden Director (Nation Health Mission I), Ministry of Health and Family Welfare
- 6. Mr Rajeev Kumar Director (NCD) Ministry of Health & Family Welfare
- 7. Dr Rajani R. Ved, Advisor (Community Processes), National Health Systems Resource Centre, New Delhi
- 8. Dr Garima Gupta, Senior Consultant (Community Processes), National Health Systems Resource Centre, New Delhi
- 9. Dr Mayank Sharma, Consultant, Ministry of Health and Family Welfare

LIST OF TECHNICAL EXPERTS

- 1. Ms. Vini Mahajan Principal Secretary, Health, Government of Punjab
- 2. Dr. Veena Dhawan, Maternal Health Division, Ministry of Health and Family Welfare
- 3. Dr. Mohammed Shaukat, Deputy Director General, MoHFW
- 4. Dr. Sudhir Gupta, Additional Deputy Director General, Ministry of Health and Family Welfare
- 5. Dr. Bela Shah, Sr. Deputy Director General, Indian Council of Medical Research (ICMR)
- 6. Prof. Arvind Rajwanshi, HOD Gynaecology Pathology, Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh
- 7. Dr. N. V. Kamat, Principal Advisor, Indian Medical Association
- 8. Dr. Sudeep Gupta, Deputy Director, Tata Memorial Centre (TMC), Mumbai
- 9. Dr. Prashant Mathur, Director, National Centre for Diseases Informatics and Research (NCDIR), Indian Council of Medical Research (ICMR)
- 10. Dr. A Nandakumar, Director in-charge, NCDIR, Indian Council of Medical Research (ICMR)
- 11. Dr. Amar Bhatnagar, HOD Cancer Surgery, Safdarjung Hospital
- 12. Dr. D K Shukla, Scientist G, Indian Council of Medical Research (ICMR)
- 13. Dr. Tanvir Kaur, Scientist F, Indian Council of Medical Research (ICMR)

- 14. Dr. Ravi Mehrotra, Director, National Institute of Cancer Prevention and Research
- 15. Dr. Sanjay Gupta, ICPO, Indian Council of Medical Research (ICMR)
- 16. Dr. Roopa Harisprasad, ICPO, Indian Council of Medical Research (ICMR).
- 17. Dr. Shalini Gupta, CDER, All India Institute of Medical Sciences (AIIMS)
- 18. Prof. G K Rath, Chief, Dr. B.R. Ambedkar Institute-Rotary Cancer Hospital, All India Institute of Medical Sciences (AIIMS)
- 19. Dr. Neeraja Bhatla, Professor, Department of Obstetrics and Gynaecology, All India Institute of Medical Sciences (AIIMS)
- 20. Prof Anurag Srivastava, Department of Surgical Disciplines, All India Institute of Medical Sciences (AIIMS)
- 21. Prof Lalit Kumar, Dr. B.R. Ambedkar Institute-Rotary Cancer Hospital, All India Institute of Medical Sciences (AIIMS)
- 22. Dr. Naseem Shah, Centre for Dental Education and Research, All India Institute of Medical Sciences (AIIMS)
- 23. Prof. Mahesh Verma, Director- Principal, Maulana Azad Institute of Dental Sciences (MAIDS)
- 24. Dr. Sangeeta Talwar, Prof HOD, Maulana Azad Institute of Dental Sciences (MAIDS)
- 25. Dr. Renu Garg, Regional Advisor, SEARO, World Health Organization (WHO)-India
- 26. Dr. Atreyi Ganguli, National Professional Officer, World Health Organization (WHO)-India
- 27. Dr. Fikru Tullu, Acting Coordinator Health Programs, WHO Country Office India
- 28. Dr. Pratima Mittal, Professor and Head, Department of Obstetrics and Gynaecology, VMMC-Safdarjung Hospital
- 29. Prof. J S Thakur, Professor, School of Public Health, Postgraduate Institute of Medical Education and Research (PGIMER)
- 30. Dr. R. K. Grover, Director and CEO, Delhi State Cancer Institute

- 31. Dr. K. K. Aggarwal, Honorary Secretary General, Indian Medical Association
- 32. Dr. Puspha Singh, Professor and Head, Department of Obstetrics and Gynaecology, Dr. Ram Manohar Lohia Hospital
- 33. Dr. Preet K. Dhillon, Epidemiologist, Centre for Chronic Conditions and Injuries (CCCI), Public Health Foundation of India (PHFI)
- 34. Dr. P. Raghu Ram, Association of Breast Surgeon of India, Hyderabad
- 35. Dr. O. P. Kharbanda, Dental Surgeon, All India Institute of Medical Sciences (AIIMS)

CONTENTS

List of Abbreviations	ххі
Introduction	1
Rationale	3
Objectives of the Framework document	5
Section 1: Organization of referral and treatment services	6
Section 2: Human Resource Requirements	11
Section 3: Training strategy	11
Section 4: Behavior Change Communication	13
Section 5: Programme Monitoring	13
Section 6: Financing	14
Annexures	15
Annexure 1a: Screening and Management Algorithm for breast cancer	15
Annexure 1b: Screening and Management Algorithm for cervical cancer	16
Annexure 1c: Screening and Management Algorithm for oral cancer	17

LIST OF **ABBREVIATIONS**

Auxiliary Nurse Midwife ANM

ASHA Accredited Social Health Activist

CBE Clinical Breast Examination

CHC Community Health Center

Cardiovascular disease CVD

DH District Hospital

Gol Government of India

HPE Histopathology Examination

IEC Information, Education and Communication

LEEP Loop Electro-surgical Excision Procedure

LMIC Low/Middle Income Countries

MO Medical Officer

Multipurpose Health Worker MPHW

Non Communicable Diseases NCD

NPCDCS National Programme For Prevention and Control of Cancer, Diabetes,

Cardiovascular Disease and Stroke

OVE Oral visual examination

PHC Primary Health Centre

SC Sub Centre

TCC Tertiary Cancer Center

VIA Visual Inspection with Acetic Acid

INTRODUCTION

The International Agency for Research on Cancer, the GLOBOCAN project has predicted that the cancer burden in India will rise from nearly one million new cases in 2012 to over 1.5 million i e., 1,569,196 by 2035. These projections also indicate that the absolute numbers of cancer deaths will also rise from about 680,000 to about 1.2 million in the same period. Estimates from the data of the National Cancer Registry Programme (NCRP), Indian Council of Medical Research indicate that there are about 14 lakh incident cases, 38 lakh prevalent cases and 7 lakh cancer related deaths per year².

Costs of care for cancer treatment are high, and studies show that almost three quarters of cancer expenditure in India is paid out of pocket, despite many welfare schemes for cancer treatment from both state and central governments³. The odds of incurring catastrophic hospitalization expenditures are about 160% higher with cancer than for hospitalization costs for a communicable disease condition. The odds of incurring catastrophic spending with cancers are nearly double compared to accidents and CVD⁴. The financial catastrophe experienced by the cancer patient and her/his family on diagnosis and treatment, could likely result in psychosocial stress.

^{1.} Ferlay J, Soerjomataram I, Ervik M, et al. GLOBOCAN 2012 v1.0, Cancer Incidence and Mortality Worldwide: IARC Cancer Base No.11. Lyon, France: International Agency for Research on Cancer, 2013. http://globocan.iarc.fr

^{2.} Indian Council of Medical Research. Three year report of Population Based Cancer Registries, 2012-2014. Bangalore: National Centre for Disease Informatics and Research/National Cancer Registry Programme, 2013, 2016

^{3.} Pramesh CS, Badwe RA, Borthakur BB et al. Delivery of affordable and equitable cancer care in India. LancetOncol. 2014 May;15(6):e223-33.

^{4.} Ajay Mahal et al 2010, The Economic Implications of Non-Communicable Disease for India, accessed from http://siteresources.worldbank.org/HEALTHNUTRITIONANDPOPULATION/ Resources/2816271095698140167/EconomicImplicationsofNCD for India.pdf

Several states have developed schemes for early detection of cancer, and access to treatment through social protection schemes. The National Programme for Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS), programme which is also funded through the National Health Mission, began with screening and early diagnosis, through an opportunistic screening approach at the level of the Community Health Centre and the District Hospital, with treatment being provided at the Regional Cancer Care Centres or medical colleges.

The three most commonly occurring cancers in India are those of the breast, uterine cervix and oral cavity. Together they account for approximately 34% of all cancers, and hence are a public health priority in India¹.

Ferlay J, Soerjomataram I, Ervik M, et al. GLOBOCAN 2012 v1.0, Cancer Incidence and Mortality Worldwide: IARC Cancer Base No.11.Lyon, France: International Agency for Research on Cancer, 2013. http://globocan.iarc.fr

RATIONALE

Survival rates for all three cancers are good, provided they are detected and treated in the early stages⁵. Thus for example, the five year survival rates for early stage cancers are 60.2%, 76.3% and 73.2% for oral, breast and cervical cancers respectively. The prognosis for advanced stage on the other hand is poor, with five year survival rates being 3.3%, 14.9%, and 7.9% for these cancers.

According to GLOBOCAN 2012, India accounts for 7.2% of global cancer incidence, but in terms of mortality, India accounts for 8.3% of global mortality. This highlights the fact that cancers in India tend to be detected late, leaving little opportunity for effective management and patient survival.

Each of these three cancers is amenable to early detection and treatment, reducing the burden of cancer related mortality and morbidity. Additionally, cancers of the oral cavity and cervix are amenable to secondary prevention because they can be detected and addressed at precancerous stages through screening using cost effective techniques.

Oral cancers are preceded by disorders that can be readily detected in the oral cavity because of an easy access of the site. Early detection of these lesions is possible during routine general health check-ups/screening by doctors/dentists/health workers or by self-examination. Clinical Breast Examination (CBE) performed by trained paramedical personnel such as female health workers is a low-cost approach to breast cancer screening for low and middle income countries. It has been suggested that given the late stage of diagnosis, average size of tumour at detection and socio-economic realities of a developing country such as India, CBE may be a viable modality for initial, baseline

^{5.} Sankaranarayanan R, Swaminathan R, Brenner H, et al. Cancer survival in Africa, Asia, and Central America: a population-based study. Lancet Oncology, 2010; 11: 165–73.

screening of breast cancer. Cervical cancer is preventable if precancerous lesions are detected and treated, thus preventing their progression to invasive cancer. Cervical cancer incidence reduces dramatically when effective screening programs linked with access to treatment are in place and are readily accessible. For this reason, cervical cancer screening programs are life-saving and cost-saving interventions that can greatly improve the quality of life for the women of India. Of the available visual screening tests, visual inspection using acetic acid (VIA) has been most widely investigated and accepted as a potential alternative to cytology in low resource settings.

The current strategy under the NPCDCS programmes relies on opportunistic screening. However in our country given the significant information asymmetry that exists and low levels of health awareness, screening for diseases where there are no obvious symptoms is perceived to be an unnecessary process, particularly so amongst the poor, for whom a day's visit to the secondary or tertiary facility for screening, might mean the loss of a day's wages.

Instituting population based screening at the sub centre for these three cancers would be particularly beneficial to women, given current levels of care seeking among women and limited access to health services. Under NHM, population based screening including for the three cancers is being initiated as part of comprehensive care which would complement the NPCDCS. Recent increases in institutional delivery and improved use of contraception, notwithstanding, attention to other aspects of women's health has historically been low. Such screening programmes would also address the issue of equity, since population based screening would also enable reach to the marginalized, who are also excluded from health care services on account of poverty and other forms of marginalization.

Thus in order for screening programmes to be easily accessible, particularly for women and other vulnerable groups, they need to be decentralized to a level of care as close as possible, and be undertaken on a population wide level for particular age categories. Population based screening programmes also serve the purpose of increasing awareness in the community about cancers, risk factors and the need for periodic screening. It also enables an understanding of better health and avoidance of risk factors in the general community. Effective and accessible cancer screening program ensure early detection and increase in cancer survival rates.

However, screening programmes are not an end unto themselves. Screening programmes for cancer, just as screening programmes for any other condition, require the assurance of high quality treatment at affordable costs, regular follow up and accessible follow-up management as and when required. Cancer screening programmes require assured

linkages at every level, with mechanisms in place for clinical handover and follow up, including high quality documentation processes that are accessible at any level of care at which the patient presents. Cancer screening programmes also require a well-designed information communication strategy that focuses not only on increasing cancer awareness and the benefits of screening programmes, but also on risk reduction strategies. Providers also need to be sensitized at every level on the necessity of screening for cancers opportunistically, and the importance of regular follow up at facility and community level. Finally, mechanisms would need to be established, in order to link the screening programmes to cancer registries across the country, for better information on incidence and prevalence of cancer and related morbidities. States would need to ensure that there is adequate linkage between the early detection strategy and the confirmatory diagnosis and subsequent treatment. They must also enable expanded access to care by providing cancer treatment at district level hospitals, and regional centers, rather than locate treatment centers in metro cities and medical colleges alone.

The extent, to which cancer deaths and morbidity and consequences to family, community and country can be mitigated, depends upon framing of adequate public health policies and effective implementation.

OBJECTIVES OF THE FRAMEWORK DOCUMENT

This framework is intended to provide guidance to states for the management of these three common cancers in rural and urban areas. This framework is not a stand-alone document. It builds on the Operational Guidelines for Prevention, Screening and Control of Common Non-Communicable Diseases: Hypertension, Diabetes Mellitus, and Common Cancers, (Ministry of Health and Family Welfare, June 2016), referred to hereafter as "OGs for screening for common NCDs", in this document. The operationalization of the framework also rests on the National Non Communicable Diseases monitoring Framework and the National NCD Action Plan. For operationalization, the framework relies on the existing health systems strengthening effort under the National Health Mission (NHM). The objective of the framework document is to provide guidance to states on the next steps after screening at the level of the sub centre/Primary Health Centre for the three common cancers. States should adapt this guidance to their contexts. They could also refer to other programme documents and guidelines that are intended to provide a road map for cancer treatment^{6,7}.

^{6.} http://apps.who.int/iris/bitstream/10665/94830/1/9789241548694_eng.pdf

^{7.} http://screening.iarc.fr/doc/WHO_India_CCSP_guidelines_2005.pdf

The format is as follows: In Section 1, we present the broad principles for service organization for referral and treatment. In Section 2, we discuss the Human resource requirements and in Section 3, the training strategy. We discuss the principles on which a behavior communication package should be designed in Section 4, Section 5 includes a monitoring plan, and Section 6 discusses financing. Several of these components are already included in existing programmes such as the NPCDCS and other components of NHM. So far as possible existing HR is to be utilized, but in areas where RCH loads are high, additional staff would be required, but this would vary on a case to case basis.

Section 1: Organization of referral and treatment services

A paradigm shift proposed in the OGs for Screening for common NCDs is to bring screening programmes close to the community but retaining a balance between skill mix, infrastructure and equipment availability and above all a strong and viable referral linkage to diagnosis and treatment centers at secondary or tertiary levels. Once the screening is undertaken and the service providers at the SC/PHC level identifies suspicious lesions, they would:

- Ensure timely referral of suspicious cases to the PHC/CHC/DH for further examination and confirmation by a surgeon, gynaecologist or dental surgeon, as appropriate.
- Undertake appropriate and timely follow-up of those with positive or abnormal results so that they access the services required.
- Support and enable referral of confirmed cases to cancer treatment services.

In a normative population of 1000 per village, the following age categories are to be screened:

- Oral cancer: all adult men and women over 30 years.
- Cervical and Breast Cancers: all women over 30 years.

Based on Census 2011, this works out to be 37% of women and men in this age category (188 men and 182 women). For breast cancers a much higher yield is obtained when screening women over forty years, however for programmatic and operational purposes the age for screening is being retained at 30 years for all common cancers. In the case of oral cancers, evidence from studies⁸ demonstrate greater benefit in screening those

^{8.} Sankaranarayan R et al. Effect of Screening on Oral Cancer Mortality in Kerala, India: A Cluster-Randomized Trial, Lancet 2005; 365 (9475): 1927-33.

who use tobacco in any form. Service providers involved in screening programmes will be trained to prioritize screening among those with such behaviours and also include people of younger age groups in screening programmes.

- (i) As has been described in the OGs for Screening for common NCDs, the first level screening is to be undertaken by the ANMs/Mid level providers at the Health and Wellness Centers (Sub centers), and by staff nurses at the PHCs. The aim is to ensure that screening for all cancers is provided as close to the home as possible by competently trained personnel in well equipped facilities and ensuring privacy. Working towards this aim, in every district, a mix of PHCs and sub centers/Urban PHCs/Urban CHCs would be selected so that the population coverage envisaged annually over the three-year time frame is achieved.
- (ii) ANMs would be trained in Visual examination of the oral cavity and clinical breast examination. They would also be trained in Visual inspection using Acetic Acid (VIA) for CaCx screening. In those PHCs where screening will be conducted, MOs and Staff nurses would also be trained. Staff Nurses and Medical Officers at all facilities: PHC,CHC and DH would also be trained in these methods, so as to serve as mentors and trainers to the next lower level and also assist when there are shortages/absences.

Table 1: Screening and follow up processes

Type of Cancer	Age of beneficiary	Method of Screening	Frequency of screening	If positive
Oral	30 -65 years	Oral Visual Examination (OVE)	Once in 5years	Referred to Surgeon/Dentist/ENT specialist/Medical officer at CHC/DH for confirmation* and biopsy.
Cervical	30-65 years	Visual Inspection with Acetic acid (VIA)	Once in 5years	Referred to the PHC/CHC/DH for further evaluation and management of pre-cancerous conditions where gynecologist/trained Lady Medical Officer is available.
Breast	30-65 years	Clinical Breast Examination (CBE)	Once in 5years	Referred to Surgeon at CHC/DH for confirmation using a Breast ultra sound probe followed by biopsy as appropriate.

^{*}The biopsy specimen either to be sent to the nearest Medical college or using the mechanism under the Free Diagnostics Initiative under NHM, to the nearest NABL certified laboratory.

- (iii) Where providers are trained and competent to perform cryotherapy for cancer cervix, such facilities would be strengthened to provide cryotherapy for those who are eligible based on accepted standards. Depending on state context this could be at the level of a CHC/DH where the gynecologist trained in the procedure is available. If the state chooses they could also train Lady Medical Officers at the level of the PHC to perform cryotherapy. Training of such medical officers would need to be undertaken at a tertiary centre under the supervision of a gynecologist and the medical officer would need to be certified as being competent. The session on level where cryotherapy is offered rests with the state and is based on service provider availability. All CHCs in the district would be strengthened to provide confirmatory tests for those screened and suspected of abnormal test results. We expect higher false positive rates in the first two years, until peripheral service providers gain confidence. Colposcopes and ultrasound breast probes will be provided at CHC/DH level as appropriate to state context and depending on availability of a trained provider.
- (iv) In order to roll out this component at scale, it would first need to be implemented in different contexts for better estimates of how to organize work processes in different contexts and the allocation of roles and responsibilities.
- (v) Implementation of this programme would be through the regular health system, supported by the District NCD cell for planning, monitoring and reporting. The first six months of the programme will be dedicated to planning details of the roll-out, including HR recruitment as required, developing IEC strategy, building capacity and planning implementation details specific to the state, including phasing. The key principle here is that when screening is initiated, forward and backward referral linkages must be instituted at the same time, so that there are no delays in sending those detected as positive during screening to the first level referral site for confirmation and then to the tertiary site.
- (vi) The state can roll out the program initially in selected districts (well performing NPCDCS districts) and then expand to other districts in a phased manner depending on the availability of human resources and infrastructure for screening.
- (vii) Once a district is selected, the state could decide based on levels of readiness, HR and geography, those centers at sub center and PHC levels that need to be developed as screening centers for cancer screening. These centers will be equipped to provide basic level of services, including VIA, OVE and CBE, breast health awareness, and service providers to be trained as appropriate.

The principle is that the DH and CHC in the district would be equipped for confirmation and first line of management and follow up. Till such time the CHC are equipped with the equipment and consumable required for evaluation and confirmation of screen positives, individuals with positive screening results will be sent to DH for confirmation. (Flow charts for the entire process from screening through management of all 3 cancers are at Annexes 1a-c).

(viii) Phased coverage could be planned as follows:

Table 2: Target population for screening year-wise, level-wise and type of cancer⁹

Phasing Year	Level	Oral cancer (men and women) 30-65 years	Cervical and breast cancer (all women) 30 -65 years
1 st year	Village	185	91
50% coverage	Sub Centre	925	455
2 nd year 65% coverage	Village	240	118
(1 st year + 15%)	Sub Centre	1200	590
3 rd year 80% coverage	Village	296	146
(2 nd year + 15%)	Sub Centre	1480	730

- Linkage of each screening site to facilities with diagnosis and treatment should (ix) be ensured. Therefore, each individual screened positive at the SC should be referred to the PHC/CHC/DH as relevant for confirmation, additional investigation and appropriate management.
- District hospitals should be strengthened as the 'First referral' point from CHC/ (x) PHC/SC. The District Hospital is expected to have the capacity to provide diagnostic breast ultrasound, Colposcopy, Cryotherapy, Loop Electro Surgical Excision Procedure (LEEP) and additional diagnostic services, including biopsy. In some states where the CHC has the full complement of specialists, they could also serve to undertake similar functions.
- The DH will serve as the training hub for staff of SC and PHC. The dentist/surgeon/ (xi) gynecologist will be (re) trained at the Medical Colleges. Medical officers would be trained in cryotherapy in tertiary centers/medical colleges.

^{9.} One district (based on 20,00,000 population).

- (xii) Every District hospital would be linked with the nearest tertiary center or medical college so as to facilitate referral and follow up and also as a mentoring cum support institutions.
- (xiii) Training for the team at the periphery would need to include, in addition to competencies in undertaking the screening procedure itself, skills in communication. Frontline workers and service providers need to be able to communicate not just signs and symptoms for early detection but also skills in communicating reassurance and support to individuals and family members.
- (xiv) Medical Colleges will provide training for providers from CHC and DH in appropriate management of patient referred from the screening process. These centers will provide advanced care and assessments for those referred from the district with suspicious lesions and/or confirmed cancer, initial and on-going therapy for cancer including surgical approaches, chemotherapy, and radiation therapy.
- (xv) Currently very few districts in the country have histopathology facilities. There are a few options that states could exercise to ensure that biopsy facilities can be undertaken at the level of the district itself. A histopathology lab could be set up for a cluster of districts and serve as a hub for nearby facilities. Alternatively, facilities under the Free Diagnostics Services scheme could be utilized to send the specimens to the designated centers. No matter what the choice the fundamental principle should be that the patient does not have to travel too far from her/his home, else the loss to follow up will be high. States could, in the first few years elect to enter into partnerships with credible agencies to undertake biopsy for confirmation, but the local context will determine the modality.
- (xvi) In those districts where there are no specialists are available, states could consider the possibility of including these districts in later phase after training the existing manpower in screening or recruiting specialists in these centres.
- (xvii) For confirmed cancer patients, the state will need to ensure admission/treatment at the tertiary center. Follow up of such patients would be undertaken at the DH/CHC. The principle of partnership with NGO or private sector should also be followed for treatment.
- (xviii) While screening for every individual would be undertaken once every five years, community level awareness should aim to ensure that any individual at any age group who develops symptoms should be screened at the PHC at any time. Any individual, who approaches the health facility for screening, will not be denied on any grounds.

(xix) Cancer patients: under treatment, and survivors and their family/care-givers also need support. In addition to treatment in facilities, states are encouraged to explore partnerships with organizations that provide community based palliative and rehabilitative care. States are also encouraged to create cancer support groups at the community level, with active engagement of frontline service providers, representatives of Panchayati Raj Institutions (PRI) and local community based groups.

Section 2: Human Resource Requirements

The success of the scheme is dependent on the requisite HR being in place at all levels. While the broad requirements are suggested in the table below, states would need to review the available HR and redeploy or reallocate so that the screening caseloads are adequately resourced.

Table 3: Human resource deployment for screening programmes linked to activity

Level	HR in place	Required	Activity
PHC	Medical Officer/Staff Nurse/ANM	One additional staff nurse to support the sub center teams.	VIA; hub for population records; nodal management for all Sub Centres in its coverage area; cryotherapy if there is a trained Lady Medical Officer, and to serve as a, hub for monitoring and supervision and support
CHC	Surgeon/ Gynecologist/ Dentist/Nurse	NCD cell staff could be redeployed within the facility to manage the increased workload.	Evaluation for all positives referred from periphery, Biopsy for Oral Ca; Breast ultrasound scan for suspected lumps, For VIA positive: Cryotherapy, Colposcopy
DH	Surgeon/ Gynecologist/ ENT specialist/ Pathologist/ Dentist/Nurse	Nodal officer for NCD, NCD cell staff could be redeployed within the facility to manage the increased workload.	(only if not possible at CHC) Evaluation for all positives referred from periphery, Biopsy for Oral Cancer Ultrasound probe for abnormal breast findings For VIA positive: Cryotherapy, Colposcopy, LEEP Will serve as a training hub and a centre to confirm cases, refer to tertiary centre for treatment

Section 3: Training Strategy

(i) A cascade approach to training would be followed for all cadres of service providers. The goal is to ensure that key competencies are built for the provider at each level of facility, to undertake the required screening or confirmatory procedure. In addition, providers would need to be trained in the skills of communication of positive results and reassurance to patient and family for those detected to be positive at the screening. Frontline providers particularly need training in support and follow up for cancer patients, since those treated for cancer would need follow up care at these peripheral levels.

- (ii) Training would cover the following areas:
 - Understanding the concepts and operational details of the programme at all stages.
 - Understanding cross linkages with existing programmes and skills in leveraging resources across programmes.
 - Building skills and competences in skills for screening and for confirmatory tests for those who would be undertaking the procedures.
 - Communication and counseling skills
 - Work flow processes at various levels
 - Recording and Reporting
 - Referrals
 - > Follow up at community level
- (iii) Three cadres of trainers are envisaged: national, state and district:
 - National Trainers: These would be a cadre of trainers drawn from Medical College/Research Institutes across the country: -Gynecologists, Surgeons, Dentists. Through a two day programme, they would be oriented to the programme and trained in standardizing their own skills and being able to build capacity in these competencies for their counterparts at state levels. Nodal agencies for the training at the national level would include the Directorate General Health Services, the National Institute for Cancer Prevention and Research (NICPR), National Institute of Health and Family Welfare, and the National Health Systems Resource Center.
 - State Trainers: These would include gynecologists, surgeons, pathologists, dentists and staff nurses from the tertiary level institute/Medical college training Centre of the State and also from the districts. These trainers would need to undertake training of district and sub district teams. A team of

about four trainers per three districts should be identified. The State level Trainers would be trained at a state medical college for about ten days in programmatic orientation, including supervision of training in districts, and orientation for standardization of technical and clinical skills and skills in training district trainers.

- For Lady Medical Officers, selected to undertake cryotherapy, a six-day training with hands on practice in a tertiary center under the supervision of a gynecologist.
- Orientation of State and District Level Officials and Stakeholders: This involves training of stakeholders who would be involved in rolling out of the initiative in their respective states and districts. This would require the organization of a one day orientation workshop on the oral, breast and cervical cancer diagnostic and management modalities and the linkages to the screening programme. The participants of these State and District Level Orientation meetings will be the Health and Medical Education Directorate officials, State RCH/RMNCH+A Officials, Civil Surgeons, Dy. Civil Surgeons, Facility in charges, District Programme Managers.

Standard treatment quidelines would be updated and disseminated periodically.

Section 4: Behavior Change Communication

While the OGs for Screening for Common NCDs address the issue of BCC in general, a communication strategy for those who are suspected of cancers would be included. Such individuals need to be aware of issues such as Treatment options and levels of care, Social protection schemes and other treatment options that would cover the costs of care, support networks and programmes to address habits such as tobacco and alcohol consumption, and likely complications of their conditions. Effective interpersonal communication would be part of training programmes for all providers. Increasing levels of literacy allow for use of patient education leaflets to be distributed at the screening sites. This is to be complemented by person-to-person and group health education, and using platforms such as the Village Health and Nutrition Day (VHND).

Section 5: Programme Monitoring

The monitoring framework for NPCDCS already includes key indicators for measuring programmatic progress and these would be adapted to the framework. Large scale

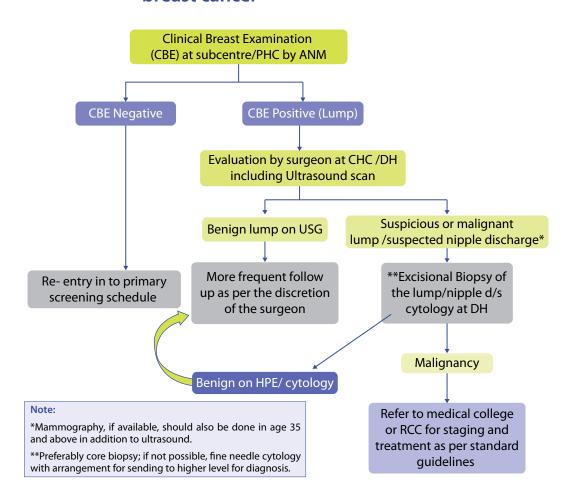
periodic surveys such as the National Family Health Survey (NFHS), National Sample Survey Organization (NSSO), District Level Household Surveys (DLHS), etc., would be used to assess effectiveness of the programme through cancer incidence and cancer related mortality rates, access to screening, changes in tobacco and alcohol consumption, population obesity levels, etc.

Section 6: Financing

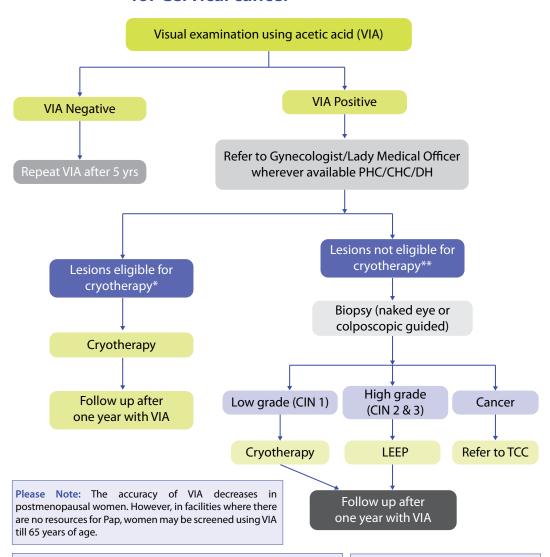
The NPCDCS programme already provides support for several interventions proposed in this framework. Additional costing details for this initiative would be provided to states separately. States are also encouraged to leverage existing schemes under NHM and state level health protection schemes and to protect end users from any financial hardship.

ANNEXURES

Annexure 1a: Screening and Management Algorithm for breast cancer



Annexure 1b: Screening and Management Algorithm for Cervical cancer



*Eligibility for cryotherapy:

- The lesion should not be spread over more than 2 quadrant of cervix
- > The entire lesion is located in the ectocervix without extension to the vagina and/or endocervix
- > The lesion is visible in its entire extent
- > The lesion can be adequately covered by the largest available cryotherapy probe
- > There is no suspicion of invasive cancer

**Cryotherapy not recommended if:

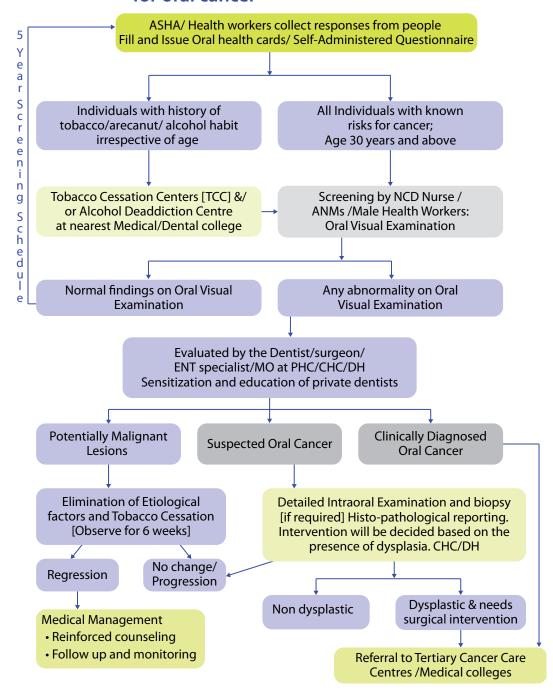
Symptoms:

- 1. Postcoital bleeding
- 2. Postmenopausal bleeding

Examination:

- 3. Overt cervical growth
- 4. Irregular surface
- 5 Bleeds on touch

Annexure 1c: Screening and Management Algorithm for oral cancer





National Health Mission

Ministry of Health and Family Welfare Government of India