

### Introduction and Background

The National Cancer Control Programme (NCCP) was initiated in the year 1975, through partial support to Regional Cancer Centres. The approach was widened in 1984-85 as well as during 1995, with emphasis on primary prevention and early detection of cancers. The schemes under NCCP were modified during the 10<sup>th</sup> five-year plan period. The data from the National Cancer Registry Programme suggests that approximately 8 lakh new persons are affected by cancer every year in India. Cancer experts feel the need for wide spread preventive and early diagnostic activities in the country, with adequate backup with curative facilities. However, the current allocation is not expected to provide an adequate cover with above approach, leave alone the evidence based approach of cancer screening for common cancers like cervix, breast and oral cavity. Thus, NCCP deserves far more financial resource to show any improvement in the current situation of 8 lakh incident cases and about 4.0 lakh annual deaths.

A meeting of the National Task Force Core Group of the Ministry of Health & Family Welfare for formulating strategies for the NCCP for the 11<sup>th</sup> Five Year Plan, was held on 27<sup>th</sup> October 2005. The Core Group recommended constitution of four groups to discuss and prepare background documents related to, (i) Cancer Control, Prevention & Early Detection, and Human Resource Development for Cancer & Cancer Registry; (ii) Cancer Treatment (with subgroups on Radiation Oncology, Medical Oncology & Surgical Oncology); (iii) Palliative Care and Rehabilitation; and (iv) Cancer Research. The Coordinator of the Group on Research for NCCP was Dr. Bela Shah, with Dr. Kishore Chaudhry being the Convener. Dr. Rajiv Sarin prepared a background paper for the Group, which provided current scenario on cancer magnitude and control in India. A format for sending the views was also prepared by the Division of NCD (ICMR). The background paper was circulated to all the members who were requested to send their views by email. In view of the financial constraints a smaller group met on 9<sup>th</sup> January 2006 at ICMR headquarters, New Delhi and provided inputs for areas of research. The members of the Group are given at Annexure 1. The current document prepared by the Coordinator and the Convener, based on the discussions and suggestions during the meeting of the Group and suggestions from other experts in the field.

So far the NCCP has mainly concentrated on service related activities. Limitations also exist on evaluation and monitoring of existing NCCP activities. However, it has been observed that common cancers of the country, like oral cavity, cervix, etc., are mainly a problem of India or developing countries and the suggestions from developed world

may or may not be feasible or practical for the country. Operational research projects by ICMR have clearly shown the feasibility of undertaking activities related to cervical cancer screening as well as anti-tobacco community education through utilization of existing infrastructures. The research studies also highlighted the need for further research which could help in faster application of newer knowledge for cancer control. In view of this, the Core Group recommended building a component of cancer research under the 11<sup>th</sup> five-year plan of NCCP.

## II. Objectives

The Task Force Core Group for formulating strategies for the National Cancer Control Programme during its meeting on 27<sup>th</sup> October 2005, finalized the following Terms of Reference for all the Groups:

1. To review the current strategy for cancer control
2. To develop a comprehensive strategy for the 11<sup>th</sup> Plan period 2007-2012
3. To develop a strategy to create awareness on the link between cancer and risk factors such as tobacco, diet etc.
4. To identify resources as regards manpower, material and finance
5. To ensure geographical balance in availability of cancer care facilities and develop cancer care institutions in underserved/ un-served areas in the country
6. To identify and strengthen the components of the NCCP
7. Identify strategies to evaluate and monitor the implementation of the Programme
8. To ensure sustainability
9. To study the alternate Financing Options
10. To devise mechanisms for ensuring Community Participation, Ownership, etc.

The Task Force Core Group had also suggested that the Groups should consider achievable and measurable objectives; equipment and infrastructure requirements; needs for manpower training; logistics for enhancement of facilities; better data availability; promotion of community-oriented and clinical research as relevant to the conditions in the country; strategy for monitoring and evaluation of the programme; and the need for network across the country through Onconet. Special focus should be on cancer prevention, early detection, childhood cancers and cancer registration, with equitable distribution in the country.

The Terms of Reference as suggested by the Core Group related to all the Groups and mainly had service activities in mind. However, the Group on Research for NCCP considered them wherever relevant.

### III. Strategies and Major Areas for Research for NCCP

It is important that the direction of research for NCCP should be in line with the control activities proposed during the 11th plan period. Thus, only those recommendations which may have a possibility of implementation during 11th or 12th five-year plan period. Suggestions which may add to existing knowledge but may require further research to fine tune to community requirement may separately be considered by ICMR, under its own research plan.

Priority cancers for the country are that of cervix, head & neck, breast, prostate, gall bladder, lung and haematological cancers, and should be considered for research to supplement NCCP.

#### A. Cancer Registration

**Expansion of Network:** The current network of the National Cancer Registry Programme (NCRP) of ICMR includes 14 population based and 5 hospital based cancer registries. While the North-Eastern India has been covered under the project to a fair extent, there is a need for expansion to rest of India. Some population based cancer registries are functioning outside the NCRP network. It is important that these registries are brought under the network of NCRP, in order to ensure standardized data collection by all the registries. It would be useful for evaluation of NCCP and also for faster generation of research hypotheses, if some registries function at state level. Extension/ initiation of state level registries in Maharashtra, Himachal Pradesh, Uttar Pradesh, West Bengal, Kerala, and Madhya Pradesh, may help in providing useful national level data which would help in NCCP. State level cancer registries have already been initiated in Sikkim and Mizoram. With the expansion as given above, the NCRP would have 8 state level and 14 other population based cancer registries.

Establishment of Hospital Based Cancer Registry in each of the Regional Cancer Centres is important and would help in evaluation of their therapeutic activities. The Medical Record Sections of RCCs could be tuned to act as hospital cancer registries in view of similarity of functioning. This should be done as an integral activity of RCCs.

One of the pre-requisites for any national programme implementation is availability of standardized and validated data on incidence/ prevalence, morbidity/ severity, mortality and time trends. The NCRP fulfills this need of the NCCP. The data from NCRP has been extremely useful in planning of NCCP and would help in monitoring and evaluation of intervention activities. Therefore the entire budget of NCRP should be met from NCCP. The estimated budgetary requirement for this project during the 11<sup>th</sup> plan period is Rs. 75.0 Crore (approximately Rs. 13 crore per year).

Calculation of current and projected (including mathematical modeling) cancer burden and mortality for major sites as well as for all sites combined, would be an important

activity of NCRP to provide balanced data which reflected the current and projected scenario of cancer occurrence for the country. No additional budget is required.

Targets during 11<sup>th</sup> plan period should aim at reduction of incidence and mortality rates and increase in the proportion of stage I&II disease at the time of detection. This information can be collected from the registries. Exercises to assess population based survival data would also be attempted by the NCRP

The estimated budgetary requirement for this project during the 11<sup>th</sup> plan period is Rs. 75.0 Crore.

## **B. Operational Research**

Operational research activities are important to test the feasibility, practicality and cost-effectiveness of newer strategies for control of common cancers of different regions of the country.

**Cancer Screening:** Cancer screening has globally been identified as the most effective means of early detection of cancers and thereby reduction of incidence/ mortality rates due to cancers. The ICMR has initiated a project in 3 districts of Himachal Pradesh on screening for cancers of cervix, breast and oral cavity, through involvement of State health services. A similar screening project has been initiated by Tata Memorial Centre in 3 districts of Maharashtra, although with separate staff for screening. It is proposed to initiate similar projects in Southern and Eastern parts of the country, through involvement of health services. The project would provide important inputs on the feasibility and operationalization of cancer screening in the country. The study would also help in identification of high-risk groups relevant to India.

The estimated budgetary requirement for two additional centers of the project during the 11<sup>th</sup> plan period is Rs. 25.0 Crore.

**Newer Approaches for Early Detection and Management:** Many of the existing modalities for early detection are considered to be either too costly or require intense training and quality control. The failure of Pap smear screening programme in some countries of Southern America is considered to be due to lower quality of services. It is important to identify simpler tests with lesser need for accuracy of examination or reading of the test. Some promising leads include visual examination of cervix after application of acetic acid and/or Lugol's iodine, screening for HPV, etc. It is important to identify such tests and try them in the field to assess the possibility of their inclusion in the health services.

The estimated budgetary requirement for this project during the 11<sup>th</sup> plan period is Rs. 20.0 Crore.

**Carcinogen Reference Laboratories:** Environment accounts for a large number of risk factors in causation of cancers. It is therefore important to know the role of various carcinogens in the environment. It is also important to monitor the levels of various known carcinogens and understand their role and quantum in causation of cancer. Such centers would also help in identifying newer carcinogens and providing guidelines for their control and permissible levels. Three such centers are proposed to be set up in different parts of the country.

The estimated budgetary requirement for this project during the 11<sup>th</sup> plan period is Rs. 15.0 Crore.

**Study on Cost of Major Sites of Cancers:** Economics plays a major role in institution of intervention activities, including tobacco control and initiation of cancer screening activities. The ICMR during 1990s carried out a study on cost of major tobacco related diseases, which showed that the cost of three major disease entities due to tobacco (cancers, coronary heart disease & chronic obstructive pulmonary diseases) was higher than the sale value of all the tobacco products in India. This study considered the direct as well as indirect costs to the country caused by use of tobacco. Initiation of such studies would help in understanding the cost-effectiveness of intervention programmes.

The estimated budgetary requirement for this project during the 11<sup>th</sup> plan period is Rs. 3.0 Crore.

### C. Risk Factors

**Determination of Prevalence of Major Risk Factors for Common Cancers:** Multi-centric studies aimed at assessing the prevalence of major risk factors would help in assessing the possible direction of change in the incidence of cancers caused by them. Data on tobacco use would help in planning for the preparedness for other diseases caused by tobacco, like coronary heart disease, chronic obstructive pulmonary disease, stroke, etc. Behavioural profiling of the target population under study would also help in developing focused intervention strategies. The results are expected in cost-effective utilization of resources for control programmes under NCCP.

The estimated budgetary requirement for this project during the 11<sup>th</sup> plan period is Rs.30.0 Crore.

**Role of Diet in Aetiology of Cancer:** Diet is an important risk factor in causation of many cancers like breast, prostate, ovary, etc. Deficiency of many nutrient is also considered to be contributing to causation of cancers. It is important to understand the role of common India dietary elements in aetiology of common cancers. As usual of food frequency methods have not helped in fully understanding of aetiology, it is proposed to initiate a cohort study on understanding the role of diet in causation of

common cancers in India scenario. The study may be carried out at 5 centres in different parts of the country.

The estimated budgetary requirement for this project during the 11<sup>th</sup> plan period is Rs. 15.0 Crore.

**Role of Plain Pan Masala and Other Non-tobacco Mixtures in Aetiology of Oral Cancer:** Use of areca nut is a sensitive issue in the country. In the recent years it has also been recognized that plain pan masala may be an important areca nut mixture, which needs to be studied regarding its role in causation of oral pre-cancers and cancers. A study on initial baseline survey on this aspect has been submitted by ICMR to the Ministry of Health & Family Welfare. It is [proposed to build a component of follow up to fully understand the role of various tobacco and non-tobacco factors in causation of oral pre-cancerous lesions and their transformation to cancers.

The estimated budgetary requirement for this project during the 11<sup>th</sup> plan period is Rs. 5.5 Crore.

**Chemo-prevention with Plant Products:** Many of common India plant products have been recognized as possible chemo-preventive agents in aetiology of cancers. Some of these known plant products, include, turmeric, grapes, garlic, ginger, plumbago, chitra, ocimum sanctum, etc. However, their role and efficacy in aetiology of cancers is still uncertain and needs careful testing. It is proposed to build such studies within some of the operational research projects, to cost-effectively study their efficacy for chemo-prevention.

The estimated budgetary requirement for this project during the 11<sup>th</sup> plan period is Rs. 2.0 Crore.

#### **D. Cancer Management**

**Management Guidelines for Common Cancers:** Different guidelines have been set up by different international bodies for management of cancers. Indian scientists believe that these guidelines may not be appropriate for Indian cancer patients in view of their inherent differences or tolerability to some drugs. It has also been observed that oral cancers have guidelines as a whole, while different sites need specific guidelines under Indian scenario. It is important to develop optimum and also minimal clinical management recommendations for the country. The ICMR has initiated a review of existing guidelines for buccal mucosa cancer and for chronic myeloid leukaemia. It is proposed to expand this activity to include most cancer sites. The exercise would help in identifying new approaches for wider availability of curative facilities, and would also address holistic palliative care as well as quality of life as suited to India. This would not only help in optimum treatment of patients, but also avoid confusion among oncologists and provide guidelines for a public health approach towards the problem.

The estimated budgetary requirement for this project during the 11<sup>th</sup> plan period is Rs. 1.0 Crore.

**Tools for Measurement of Quality of Life of Cancer Patients:** Appropriate tools need to be devised the measurement of quality of life of cancer patients among Indian patients. The need has been realized by oncologists, in view of differences in social and cultural aspects.

The estimated budgetary requirement for this project during the 11<sup>th</sup> plan period is Rs. 0.5 Crore.

**Development of New Herbal Drugs:** A comprehensive research programme on development of new herbal drugs for treatment of cancer (either for mainline therapy or as an adjunct), is expected to help in better and cheaper management of cancer cases. Leads from indigenous system of medicines, would help in identifying promising substances. The programme would help in further standardization of methods of production, optimum dosage schedule, etc. Clinical trials on important leads would help in assessing their role in management of common cancers. Department of AYUSH would have an active role in this activity.

The estimated budgetary requirement for this project during the 11<sup>th</sup> plan period is Rs. 25.0 Crore.

**To evaluate the effectiveness of educational interventions for doctors, nurses and social workers:** While the development of such material may be carried out as an intervention activity, development of innovative strategies for this purpose may be considered as a research activity.

#### **E. Suggestions which may be considered as intervention programmes under NCCP**

Certain research areas may be considered as areas on borderline with intervention modalities. These may be considered by other groups. If other groups feel that these are still research aspects, these may be considered under research activities. Some suggestions from the groups consulted are given below.

Assess the status of Narcotics Law in different states and need for its assessment in connection with palliative and supportive care for cancer control, including professional training for this purpose.

Impact of vocational rehabilitation for cancer survivors/ bereaved family members.

To study the value of complementary interventions, like alternative and indigenous therapies, psycho-social and counseling interventions, physical and vocational rehabilitation interventions.

Development of cost-effective palliative regimens, (radiotherapy or chemotherapy or surgery based), including development of guidelines for this purpose.

Identify methods to increase compliance to treatment of cancer.

Addressing emotional distress by training in communication skills and by networking support groups with health professionals.

Availability of effective pain relief services for cancer patients.

### **Suggestions F. Research by ICMR (budget not provided)**

Certain areas suggested by various groups are considered to be major research areas which should be considered by ICMR. In case the group considers that some of these areas should be funded by NCCP, changes may be made. Some suggested areas are given below.

Reduction of drug toxicity experienced during cancer management.

Creation of a comprehensive catalogue on genetic changes observed during carcinogenesis.

Evaluation of new therapeutic approaches based on molecular targets.

Research on pharmacogenomics.

Identification of bio-markers associated with development of cancer due to tobacco use (molecular epidemiology), especially of common cancers like oral cancer.

Clinical trials for comparison of efficacy of costly Vs cheaper therapeutic regimens for possible development of guidelines under NCCP, say COPP Vs ABVD for Hodgkin's lymphoma.

Ayurvedic research and leads need to be promoted.

Development and clinical trial of vaccines against cancer.

Establishment of a bio-repository to store malignant tissues and blood samples from cancer patients

Development of indigenous drugs.

Research on aetiopathogenesis and understanding the biology of cancers.

Identification of bio-markers in early detection and progression of oral pre-cancers to oral cancers.

Aetiological factors among patients of cancer tobacco related sites without history of tobacco use

Aetiology and pathogenesis of breast cancer.

Research on aetiology of cancer of gall bladder

Research on aetiology of cancer of urinary bladder.

Research on haematological cancers.

### Budget for Research Activities under National Cancer Control Programme during 11<sup>th</sup> Five-Year Plan Period

Project	Budget for Eleventh Plan Period (Rs. in lakhs)					Budget for 11 <sup>th</sup> Plan (Rs. in lakhs)
	07-08	08-09	09-10	10-11	11-12	
National Cancer Registry Programme	2100	1350	1350	1350	1350	7500
Cancer Screening	900	400	400	400	400	2500
Newer approaches for early detection	400	400	400	400	400	2000
Carcinogen Reference Laboratories (3)	300	300	300	300	300	1500
Cost of Major Cancers	60	60	60	60	60	300
Prevalence of Major Risk factors	600	600	600	600	600	3000
Diet and Cancer	300	300	300	300	300	1500
Plain pan masala and oral cancers	150	100	100	100	100	550
Chemo-prevention with plants	0	50	50	50	50	200
Minimal Cancer Management Guidelines	40	30	30	0	0	100
Quality of Life of Indian Cancer Patients	0	0	10	20	20	50
Development of New Herbal Drugs	500	500	500	500	500	2500
Total	5350	4090	4100	4080	4080	21700

### Members of the Group on Research for National Cancer Control Programme of India, constituted by the Ministry of Health & Family Welfare

#### A. Members who participated in the Meeting of the Group held at ICMR Headquarters, New Delhi, on 9<sup>th</sup> January 2006

1. Dr. Bela Shah, Sr. DDG, ICMR, New Delhi Coordinator
2. Dr. Kishore Chaudhry, DDG (SG), ICMR, New Delhi Convener
3. Dr Indira Chakraborty, Dean and Director Professor, All India Institute of Hygiene and Public Health, 110, Chittaranjan Avenue, Kolkata 700073.
4. Dr. Rita Banerjee, Scientist D, Department of Science and Technology, Technology Bhawan, New Mehrauli Road, New Delhi 1100016.
5. Dr. Bindu Dey, Director, Department of Biotechnology, Block-2 (6-8th Floors) CGO Complex, Lodi Road, New Delhi - 110 003.
6. Dr. G.S. Lavekar, Director, Central Council for Research in Ayurveda and Siddha, New Delhi.
7. Dr. Vinod Katoch, Dy. Advisor, Department of AYUSH, Ministry of Health & Family Welfare, New Delhi
8. Dr. Vinod Kochupillai, Chief, Dr. Ambedkar Institute Rotary Cancer Hospital, All India Institute of Medical Sciences, Ansari Nagar, New Delhi 110029.
9. Dr T Rajkumar, Scientific Director, Cancer Institute (WIA), Adyar, Chennai 600020
10. Dr PC Gupta, Director, Healis Sekhsaria Institute of Public Health, 601, Great Eastern Chambers, Plot No. 28, Sector 11, CBD Belapur, Navi Mumbai 400614.
11. Dr. Rajiv Sarin, Director, Advanced Centre for Treatment Research & Education in Cancer (ACTREC), Kharghar, Navi Mumbai 410208
12. Dr Hariprakash, CI/ 3. AIIMS Campus, Ansari Nagar, New Delhi 110029.
13. Lt.Col.Vibha Dutta, Army Hospital, R&R, New Delhi
14. Dr. G.K. Rath, Professor & Head, Department of Radiation Oncology, IRCH, All India Institute of Medical Sciences, Ansari Nagar, New Delhi 110029.
15. Dr. Usha K. Luthra, Hon. Advisor (ICMR), J 202, Som Vihar, R.K. Puram, New Delhi 110022.
16. Dr. A.K. Tiwary, Deputy Secretary (NCD), Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi 110011.

17. Dr. Sadhna Bhagwat, Consultant (cancer), Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi 110011.

18. Dr. Tanvir Kaur, SRO, ICMR, New Delhi.

**B. Members who could not participate in the Meeting of the Group**

19. Dr. Balendu Prakash, VCP Cancer Research Foundation, Mandir Marg, Clement Town, Turner Road, Dehradun

20. Dr. Shilin Shukla, Honorary deputy Director (Research), Gujarat Cancer & Research Institute, Civil Hospital Campus, Asarwa, Ahmedabad-380 016. Gujarat.

21. Dr. Sudhir Gupta, CMO (NCD), Directorate General of Health Services, Nirman Bhawan, New Delhi 110011.

22. Dr. Cherian Varghese, NPO, WHO-India, Nirman Bhawan, New Delhi 110022.

23. Mr. K. Ramamoorthy, Jt. Secretary, Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi 110011.

24. Dr. R.K. Srivastava, Director General of Health Services, Nirman Bhawan, New Delhi 110011.

**C. Scientists who were requested to send their comments by email**

24. Dr. M. Radhakrishna Pillai, Director, Rajiv Gandhi Centre for Biotechnology, Thycaud P.O., Poojapura, Thiruvananthapuram 695014

25. Dr. Lalji Singh, Director, Centre for Cellular and Molecular Biology, Uppal Road, Hyderabad, 500007, A.P.

26. Dr. R.F. Chinoy, Professor and Head, Department of Pathology, Tata Memorial Hospital, Parel Mumbai 400012.

27. Dr. Kumarvel Somamsundaram, Department of Microbiology and Cell Biology, Indian Institute of Science, Malleswaram, Bangalore 560012.