



REPORT NO.

139

**PARLIAMENT OF INDIA  
RAJYA SABHA**

**DEPARTMENT-RELATED PARLIAMENTARY STANDING  
COMMITTEE ON HEALTH AND FAMILY WELFARE**

**ONE HUNDRED THIRTY NINETH REPORT**

ON

**CANCER CARE PLAN & MANAGEMENT: PREVENTION,  
DIAGNOSIS, RESEARCH & AFFORDABILITY OF CANCER  
TREATMENT**

*(Presented to the Chairman, Rajya Sabha on 12<sup>th</sup> September, 2022)*

*(Forwarded to the Speaker, Lok Sabha on 12<sup>th</sup> September, 2022)*



**Rajya Sabha Secretariat, New Delhi  
September, 2022/Asvina, 1944 (SAKA)**

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सत्यमेव जयते

**Rajya Sabha Secretariat, New Delhi  
September, 2022/Asvina, 1944 (SAKA)**

## CONTENTS

1.	COMPOSITION OF THE COMMITTEE	(i)
2.	PREFACE	(ii) - (iv)
3.	*ACRONYMS	----
4.	<p>Chapter- I Introduction : Incidence of Cancer Cases</p> <p>Chapter - II Prevention, Screening, Early Detection and Diagnosis Of Cancer Cases</p> <p>Chapter-III Institutional Framework For Cancer Care &amp; Management</p> <p>Chapter - IV Accessibility &amp; Affordability of Cancer Treatment</p> <p>Chapter - V Academic Training And Research Activities</p> <p>Chapter - VI Cancer Care Plan &amp; Research and Management in Ayush</p> <p>Chapter - VII Palliative Cancer Care and Management</p> <p>Chapter - VIII Views of the Ministries/Departments/NGO's/Private Hospitals and Private Sectors</p>	<p>1 – 12</p> <p>13 - 29</p> <p>30 - 58</p> <p>59 - 83</p> <p>84 – 107</p> <p>108 – 136</p> <p>137- 147</p> <p>148 - 165</p>
5.	RECOMMENDATIONS/OBSERVATIONS — AT A GLANCE	166 - 216
6.	*MINUTES	
7.	*ANNEXURES	

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*\* To be appended at the circulation stage*

**COMPOSITION OF THE COMMITTEE**  
**(2021-22)**

1. **Prof. Ram Gopal Yadav** - **Chairman**

**RAJYA SABHA**

2. Shri A.K. Antony
3. Dr. L. Hanumanthaiah
4. *Vacant*
5. *Vacant*
6. Dr. Santanu Sen
7. Shri A. D. Singh
8. Dr. Kanimozhi NVN Somu
9. *Vacant*
10. *Vacant*

**LOK SABHA**

11. Shrimati Mangal Suresh Angadi
12. Ms. Bhavana Gawali (Patil)
13. Shri Maddila Gurumoorthy
14. Ms. Ramya Haridas
15. Dr. Chandra Sen Jadon
16. Dr. Amol Ramsing Kolhe
17. Shrimati Kavitha Malothu
18. Dr. Sanghmitra Maurya
19. Shri Arjun Lal Meena
20. Shrimati Pratima Mondal
21. Dr. Pritam Gopinath Munde
22. Shri K. Navaskani
23. Dr. Sujay Radhakrishna Vikhe Patil
24. Adv. Adoor Prakash
25. Shri Haji Fazlur Rehman
26. Dr. Rajdeep Roy
27. Dr. DNV Senthilkumar S.
28. Shri Anurag Sharma
29. Dr. Mahesh Sharma
30. Dr. Krishna Pal Singh Yadav
31. Dr. Lorho S. Pfoze

**SECRETARIAT**

- |                             |                             |
|-----------------------------|-----------------------------|
| 1. Shri Mahesh Tiwari       | Joint Secretary             |
| 2. Shri Shashi Bhushan      | Director                    |
| 3. Shri Bhupendra Bhaskar   | Additional Director         |
| 4. Shri Praveen Kumar       | Deputy Secretary            |
| 5. Smt. Harshita Shankar    | Deputy Secretary            |
| 6. Shri Rajesh Kumar Sharma | Assistant Committee Officer |
| 7. Ms. Monika Garbyal       | Assistant Committee Officer |

## PREFACE

I, the Chairman of the Department-related Parliamentary Standing Committee on Health and Family Welfare, having been authorized by the Committee to present the Report on its behalf, present this One-Hundred Thirty Ninth Report on the “Cancer Care Plan & Management: Prevention, Diagnosis, Research & Affordability of Cancer Treatment”.

2. The Committee, in its meeting held on 27<sup>th</sup> June, 2022 heard the views of the Secretary, the Department of Health & Family Welfare alongwith Director General, Health Services and Secretary, Department of Health Research on the subject.

3. The Committee in its next meeting held on 28<sup>th</sup> June, 2022 heard the views of prominent cancer institutes in the country viz. Dr. Bhubaneswar Barooah Cancer Institute (BBCI), Assam, Chittaranjan National Cancer Institute, Kolkata, National Institute of Cancer Prevention & Research, Gautam Buddha Nagar, Uttar Pradesh and National Cancer Institute, AIIMS, Jhajjar, Haryana on the subject.

4. The Committee had initially selected the subject “Affordability of Cancer Treatment”<sup>1</sup>. The Committee felt the need to make a meticulous assessment of the Cancer care plan and management of cancer treatment for making comprehensive and detailed recommendations in order to restrict the growing incidence of cancer and providing affordable quality care to cancer patients in the country. Accordingly, the Committee, in its meeting held on 28<sup>th</sup> June, 2022 decided to broaden the scope of its study from the ‘Affordability of Cancer Treatment’ to "Cancer Care Plan & Management: Prevention, Diagnosis, Research & Affordability of Cancer Treatment"<sup>2</sup>.

5. The Committee, in its meeting held on 7<sup>th</sup> and 8<sup>th</sup> July, 2022, further heard the views of the Departments/Institutes viz. Department of Atomic Energy, Department of Biotechnology, Department of Pharmaceuticals and Regional Institute of Medical Sciences (RIMS), Imphal, Manipur.

6. The Committee extensively deliberated upon the subject and also sought the written views of various Departments/organizations/associations and received submissions from Department of Pharmaceuticals, Ministry of Ayush, Ministry of Environment, Forest and Climate Change, Ministry of Information and Broadcasting, Ministry of Food Processing Industries, Integrated Health and Wellbeing Council, Delhi, Progressive Foundation, Uttar Pradesh, Amrita Vishwa Vidyapeetham, Institute of Medical Sciences, Kerala, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Kerala, Rajiv Gandhi Cancer Hospital, Delhi, JIPMER, Puducherry, AIIMS, Raipur, PGIMER, Chandigarh, Indian Cancer Society (ICS), Mumbai, CAN Support, New Delhi, St. Jude India Child Care Centres, Mumbai, CAPEL, Gurugram, Cancer Foundation of India, Kolkata, Mahavir Cancer Sansthan & Research Centre, Patna, APOLLO, Delhi, FORTIS, Gurugram, Pfizer Limited, Novartis Healthcare Pvt. Limited, Roche Products (India) Pvt. Ltd., MSD Pharmaceuticals Private Limited, Confederation of Indian Industry (CII), Kidwai Memorial Institute of Oncology, Karnataka, Varian Medical Systems, Delhi on the subject.

7. The Committee undertook study visit to Kolkata and Patna from 26<sup>th</sup> to 30<sup>th</sup> November, 2018 and visited Chhitaranjan National Cancer Institute (CNCI), Kolkata and

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<sup>1</sup> Parliamentary Bulletin Part-II No. 61175 dated 28<sup>th</sup> October, 2021

<sup>2</sup> Parliamentary Bulletin Part-II No. 62029 dated 1<sup>st</sup> July, 2022

held discussion with its Director and other officials to review the status of on-going projects and functioning of the Institute, etc. The Committee also undertook a study visit to Guwahati, Bengaluru and Mumbai from 25<sup>th</sup> to 29<sup>th</sup> April, 2022 / to take stock of current Cancer landscape in State/ top causes of Cancer in the State/ steps taken by the State Government to make the cancer treatment more affordable.

8. During the finalization of its Report, the Committee relied upon the following documents/ papers:-

- (i) Background Note received from Department of Health and Family Welfare;
- (ii) Background Note received from Department of Biotechnology;
- (iii) Background Note received from Department of Atomic Energy and Department of Pharmaceuticals;
- (iv) Background Note received from Department of Health Research;
- (v) Inputs/suggestions received from Ministry of Ayush;
- (vi) Oral Evidences tendered before the Committee by representatives of Department of Health & Family Welfare; Department of Health Research; Dr. Bhubaneswar Borooah Cancer Institute (BBCI), Guwahati; Chitranjan National Cancer Institute, Kolkata; National Institute of Cancer Prevention & Research (NICPR), Gautam Budh Nagar, Uttar Pradesh; National Cancer Institute, AIIMS, Jhajjar, Haryana; Department of Atomic Energy; Department of Biotechnology; and Department of Pharmaceuticals; Regional Institute of Medical Sciences (RIMS) and verbatim proceedings of the meetings concerned;
- (vii) Annual Report, Ministry of Health and Family Welfare (2021-22);
- (viii) Oral evidences tendered by other stakeholders and their written submissions;
- (ix) Written submissions of various Organizations/Associations;
- (x) Replies to the questionnaires received from the Department of Health & Family Welfare, Ministry of Ayush and Department of Pharmaceuticals;
- (xi) The Drugs (Price Control) Order, 2013
- (xii) The National Pharmaceuticals Pricing Policy, 2012;
- (xiii) Media Journals and Academic articles; and
- (xiv) Other relevant documents pertaining to the subject.

9. The Report is divided into eight chapters, viz: - (i) Chapter 1 deals with Introduction : Incidence of Cancer Cases, (ii) Chapter 2 deals with Prevention, Screening, Early Detection and Diagnosis Of Cancer Cases, (iii) Chapter 3 focuses on Institutional Framework For Cancer Care & Management, (iv) Chapter 4 deals with Accessibility & Affordability of Cancer Treatment, (v) Chapter 5 covers Academic Training And Research Activities, (vi) Chapter 6 explains the Cancer Care Plan & Research and Management in Ayush, (vii) Chapter 7 deals with Palliative Cancer Care and Management and (viii) Chapter 8 highlights the Views of the Ministries/Departments/NGO's/Private Hospitals and Private Sectors.

10. The Committee, in its meeting held on 8<sup>th</sup> September, 2022 considered and adopted the draft report.

11. For facility of reference and convenience, the observations and recommendations of the Committee have been printed in bold letters in the body of the Report and also reproduced at the end of the Report at ‘Observations/Recommendations of the Committee-at a Glance’ .

12. On behalf of the Committee and on my own behalf, I extend special thanks to Secretaries and officers of the (i) Department of Health and Family Welfare (ii) Department of Health Research, Department of Atomic Energy, Department of Biotechnology and Department of Pharmaceuticals etc for their useful inputs on the subject. I also acknowledge the contribution of the stakeholders for their deep insight and useful suggestions during the course of interactions. I further extend special appreciation to the officers of the Committee Section for their useful efforts in assimilating all relevant information and enabling the Committee in producing this magnificent Report.

**New Delhi**  
**8<sup>th</sup> September, 2022**  
**...Bhadra, 1944 (Saka)**

**PROF. RAM GOPAL YADAV**  
**Chairman, Department-related**  
**Parliamentary Standing Committee on**  
**Health and Family Welfare**

## CHAPTER-I

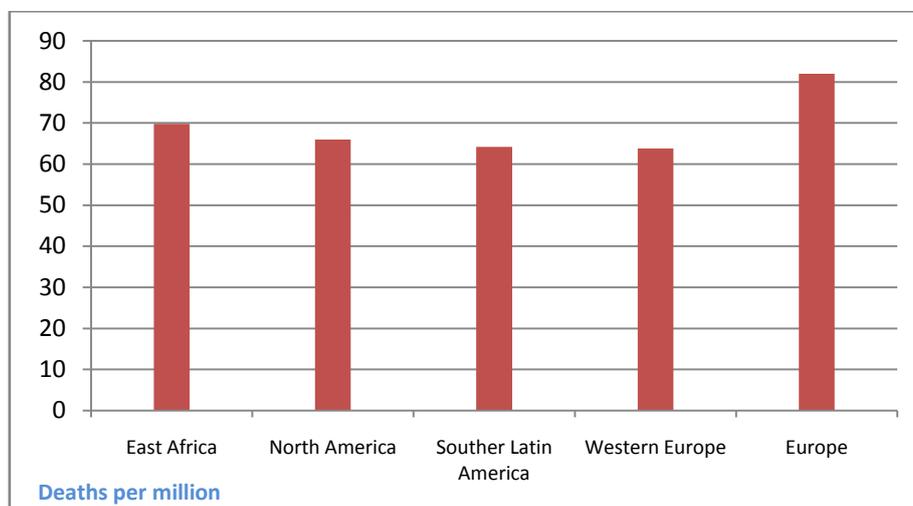
### INTRODUCTION: INCIDENCE OF CANCER CASES

1.1 The growing burden of Cancer in India triggers an urgent need to make a comprehensive assessment of the cancer treatment in the country viz. provision for prevention, screening, early detection, cancer treatment and its affordability, schemes for facilitating/supporting poor cancer patients, availability of cancer medical facilities and the required infrastructure for prevention, diagnosis, and research. The growing cases of Cancer in India are a serious concern, as it leads to not only high numbers of premature deaths but also impacts the quality of life. Cancer can affect any part of the human body, though in India, highest number of lives lost is due to oral cancer caused by tobacco followed by cancer of the lungs, oesophagus and stomach. Amongst women, breast cancer and cervical cancer is most common. It is worth noting that cancers like that of breast, cervix and oral have better prognosis if diagnosed & treated early. In order to address this serious issue, the Committee decided to examine the government's strategy on various interventions ranging from early screening and detection to facilitating affordable and comprehensive management and care of cancer patients.

#### Global Cancer Scenario

1.2 According to the recent estimation, the global number of cases will increase from 19.3 million to 28.4 million by 2040 and thus the availability of prevention and treatment options, demand a new vision.

#### Regions with most Cancer deaths



1.2.1 Using a 2019 study by the Global Burden of Diseases, injuries and risk factors, Lancet conducted a study to inform cancer control planning efforts globally. It is the first to estimate how a comprehensive list of risk factors contributes to cancer deaths and ill health globally, regionally and nationally, across age groups and for both sexes.

1.2.2 According to this research, 34 risk factors were analysed by scientists. These included tobacco use, alcohol use, unsafe sex, dietary risks, air pollution, occupational risk, low physical activity. Out of the total deaths 4.45 million cancer deaths were caused by these risk factors alone, this was 44.4% of all cancer deaths in 2019.

## Role of Gender

1.3 Researchers found that men were more likely to die of cancer than women, primarily due to two factors- behavioral risks, and environmental and occupational risks. 50.6% of all male cancer deaths are due to these risk factors only whereas for women this figure is 36.3%. Researchers further found that men are 4 times more likely to die of Cancer caused by Smoking than women; 3 times more likely to die of Cancer caused by alcohol use than women and 3 times more likely to die of Cancer caused by environmental/occupational risk than women.

1.3.1 According to Lancet commission on cancer and health systems: harnessing synergies to achieve solutions, cancer epitomises the injustices of health-care access, a decade ago the term cancer divide was used to describe the unacceptable difference in survival rates for preventable and treatable cancers across and within countries. Now, affordable, implementable solutions exist, yet survival gaps persist, exemplified by childhood cancer: in wealthy countries, 90% of children have the likelihood of cure, while in the poorest countries only 10% can hope to survive. This global health failure is perverse. For people with access to health services, science has changed many cancers into curable or liveable health conditions; where timely access to health services is lacking, survival is at best elusive. Even in high-income countries, health systems fail to offer universal access to high-quality, affordable cancer care. Despite progress, inequity in access, over diagnosis, overtreatment and escalating costs without achieving better outcomes demonstrate that cancer control in wealthy regions is no panacea. Hence, a diagonal approach to harness linkages and forge a synergistic and mutually symbiotic relationship to improve outcomes is proposed. Diagonal approaches to health-system strengthening leverage horizontal systemic programmes and policies, linking them with vertical, risk factor, or disease-specific interventions. Diagonalising cancer control can drive universal health coverage, while harnessing systemic platforms facilitates the scale-up of cancer control.

## Burden of Cancer in India Along with Growth Rate

1.4 As per the Indian Council of Medical Research's cancer registry data on "Report of National Cancer Registry Programme 2020", the estimated burden of incidence of cancer cases reported in India during the last three years is as below:-

Estimated new cancer cases in India International Classification of Diseases, Tenth Revision (ICD-10)			
Year	2018	2019	2020
Estimated Incidence (new) of cancer Cases	13,25,232	13,58,415	13,92,179

## Projected Burden of Cancer

1.4.1 In India, the burden of cancer is projected to result in a loss of 26.7 million Disability Adjusted Life Years (DALYs) in 2021 and 29.8 million DALYs in 2025. The cases are estimated to be higher in the north and north-eastern region of the country, and more among males than females. (Kulothungan, et-al BMC Cancer 2022). More than 40% of total cancer cases was contributed by cancers of lung (10.6%), breast (10.5%), oesophagus (5.8%), mouth (5.7%), stomach (5.2%), liver (4.6%) and cervix uteri (4.3%).

1.4.2 According to the memoranda submitted by the MSD Pharmaceuticals Pvt. Ltd to the Committee, the Cancer burden in India in 2020 and 2025 is given below:-

Anatomical Site	2020	2025	Anatomical Site	2020	2025
	No. of Cases (%)	No. of Cases (%)		No. of Cases (%)	No. of Cases (%)
 Tobacco Related Cancers	377830 (27.1)	427273 (27.2)	 Corpus Uteri and Ovary	70400 (5.1)	79765 (5.1)
 Gastro Intestinal Tract	273982 (19.7)	310142 (19.8)	 Lymphoid & Haemopoietic Malignancies	124931 (9.0)	138592 (8.8)
 Cervix	75209 (5.4)	85241 (5.4)	 Prostate	41532 (3.0)	47068 (3.0)
 Breast	205424 (14.8)	232832 (14.8)	 Central Nervous System	32729 (2.4)	36258 (2.3)

1.4.3 As per the Globocan Report of 2020, the annual global burden of cancer in 2020 is 1.93 crores with annual death of 1.00 crore. The projected annual new cases globally will be 2.84 crores in 2040. According to the same report, the number of new cancer cases in India will be 17.00 lakh annually by 2035.

### Cancer Registries

1.5 The Committee has been given to understand that the National Cancer Registry Programme (NCRP) under ICMR has been in existence since 1982 and is now under National Centre for Disease Informatics and Research (ICMR) since 2011. NCRP functions through Population and Hospital Based Cancer Registries (PBCR and HBCR) across different states in India. As of now there are 38 PBCRs. More than 268 Hospital Based Cancer Registries have been registered under NCDIR –NCRP. These different registries are at different geographical locations. It deals with various cancer sites in the body.

1.5.1 Only 10% of the Indian Population are covered by PBCRs. Unfortunately, large states like Uttar Pradesh, Madhya Pradesh, Rajasthan, Andhra Pradesh, Telangana, Odisha are not adequately covered by the Registry. In recent time, Centre for Cancer Epidemiology, ACTREC, Mumbai has taken initiative to expand the network of PBCR in Uttar Pradesh and Punjab. These information are important for policy makers for uniform distribution of cancer care. Cancer Registration in India faces several challenges because Cancer is not a notifiable disease, which is a major hurdle in data collection. The death registration system has several gaps including incomplete and inaccurate certification of cause of death.

**1.5.2 The Committee is constrained to express its deep displeasure over the fact that the National Cancer Registry Programme (NCRP) is working since 1982 through Population Based Cancer Registry (PBCR) and Hospital Based Cancer Registry (HBCR) but only 10% of Indian population is covered under PBCRs. The Committee strongly believes that there is an urgent need to have more rural based PBCRs to get realistic information about the incidence and type of cancers across the country. The Committee recommends National Centre for Disease Informatics and Research (ICMR)**

**to take requisite action to set up population based cancer registry in rural areas in the States viz. Uttar Pradesh, Madhya Pradesh, Andhra Pradesh, Rajasthan, Telangana, Orissa to ensure coverage of population by registry in these States. Such requisite action is all the more necessary to collect data & information not only for policy making on cancer treatment but also for uniform distribution of cancer care.**

1.5.3 The Director, Dr B Borooah Cancer Institute submitted that the National Cancer Registry Programme (NCRP) was established in 1980-81 with 3 Population Based Cancer Registry (PBCR) and 3 Hospital Based Cancer Registries (HBCR) under National Centre for Disease Informatics & Research, ICMR. In recent time, Centre for Cancer Epidemiology, ACTREC, Mumbai has taken initiative to expand the network of PBCR in Uttar Pradesh and Punjab. There is a need to have more rural based PBCRs to get realistic information about the incidence and type of cancers across the country. These information are important for policy makers for uniform distribution of cancer care.

**1.5.4 The Committee notes that Population Based Cancer Registries (PBCRs) are a critical component for cancer control strategy that facilitates accurate information on cancer burden. Realizing that PBCRs help in better planning and formulation of National Cancer Control Programmes, the Committee notes that many areas remain under represented in the existing cancer registries. The Committee therefore recommends the Ministry to take measures to expand the scope of PBCR and ensure conducting more rural based PBCRs to get accurate information about the incidence and types of cancer across the country.**

**1.5.5 The Committee recommends the Ministry to ensure that with the expansion of PBCRs, all the regions are adequately represented and an unbiased cancer registry is created. The Committee also recommends for integration of the real-time health records on a digital platform like a central registry system so that the data can be accessed across the country and there is no duplication. Such integration is crucial for better understanding of the cancer burden in the country.**

1.5.6 The Committee during its study visit to Tata Memorial Centre, Mumbai on 28<sup>th</sup> April, 2022, held discussion with the officials of TMC. During the course of discussion, TMC submitted that most of the management pathways adopted in India are based on the researches performed in the western world. Moreover, despite the efforts of the government of India, the current population -based cancer registry covers approximately 10% of the population of which rural population coverage is only 1%. That means the estimated burden of cancer and its outcome is far from satisfactory. One of the reasons for this lacuna is the lack of reporting by the hospitals, laboratories etc. to the Cancer Registry. Considering the vastness and diversity in India, the strategies for cancer care and control need a proper estimate and profound understanding that can only happen if there is an appropriate mechanism for data collection and reporting apart from accountability for the same. This can be achieved by declaring Cancer as a notifiable disease similar to what the state of Karnataka has done. TMC proposed that the notification need not be similar to that of communicable diseases with regards to punitive action following non -compliance i.e. it can be a “documentable disease” rather than a notifiable disease.

**1.5.7 The Committee notes that Cancer is still not classified as a notifiable disease which results in underreporting of cancer deaths. The Committee notes that ambiguity on the actual cause of death is a major hurdle in data collection. It has been brought to the notice of the Committee that many a times; death is simply recorded as cardio-**

respiratory failure without mentioning the actual cause of death. The Committee is of the view that an accurate mortality database in the hospital information system will improve cancer registry, follow up and outcome data. The Committee therefore agrees with the suggestion of TMC that Cancer must be classified as a notifiable disease so that the cancer deaths are mandatorily required to be reported to the Government machinery.

**1.5.8** The Committee strongly believes that making Cancer a "Notified Disease" will surely ensure a robust database of the cancer deaths but also help in determining the accurate incidence and prevalence of Cancer in the country. It will also help in analyzing the risk factors, implementing screening programs, and allocating proper resources to improve cancer outcomes. Data collected can also be used to formulate standard treatment guidelines that will further strengthen the continuum of cancer care. The Committee further recommends that to streamline and improve data collection a CoWIN-like web portal for the registration, real-time data collection, counselling, supportive resources for cancer care along with interactive tools can be created by the Government. The portal can also be equipped to aid those affected by cancer by guiding them through the treatment and management journey.

**1.5.9** The Committee further recommends the Ministry to ensure the linking of Cancer Registry data with Ayushman Bharat / PMJY, mortality data bases, and the Hospital Information System (HIS) would improve cancer registration, follow up and outcome data.

### Causes of Cancer

1.6 The Ministry informed the Committee about the various causes of cancer which *inter-alia* includes the factors as enumerated below:-

S.No.	Causes of cancer	Percentage of incidence of cancer cases
1.	Lifestyle related including- tobacco, Alcohol	33% of cases
2.	Unhealthy diet	33% of cases
3.	Infections	About 20% cases
4.	Hormones/Genetic cases	10-20% cases
5.	Pollution	1%
6.	Occupation	2%

1.6.1 The Ministry of Health and Family Welfare apprised the Committee about the major types and trends of cancers/Patterns of Gender specific Cancers/Specific trends (increasing/decreasing) of different types of cancer. Among males, cancers of lung, mouth, oesophagus and stomach are the leading sites (major types) across most of the registries. Among females, cancer of the breast is the leading site in 19 registry areas. Cancers of the cervix uteri is the leading site in 7 registry areas. Majority of registries showed a statistically significant increase in Age Adjusted Incidence Rate (AAR) over time with annual percentage change (APC) varying between (0.1%) in Bhopal to (3.8%) in Kamrup urban for males while (0.0%) in Delhi to (3.8%) in Kamrup urban for females. The decrease in incidence rate for cervix cancer is seen across all registries including the rural registry at Barshi while cancer of

breast, corpus uteri, ovary, lung cancers among females and colon, rectum, prostate among males shown increase across all registries.

### **High prevalence of Tobacco related Cancer (TRC) in the North Eastern States**

1.6.2 The Director, Dr B. Borooah Cancer Institute submitted that the prevalence of tobacco (45.7%) and alcohol use (22.3%) is significantly high in the North Eastern Region compared to rest of the country (BMC Public Health, 2022). Tobacco which is one of the single most risk factor for all non-communicable diseases is alarmingly high in India. The proportion of Tobacco Related Cancer (TRC) in many North Eastern States are above 50-60% in case of male and 20-40% in case of female.

**1.6.3 The Committee notes that the reason for high incidence of Tobacco related Cancer in the North Eastern Region is the high consumption of tobacco in the region. The Committee is appalled to note that tobacco consumption is as high as 60% in some North Eastern States against the National tobacco prevalence of 28%. The Committee further notes that the alcohol consumption in the North East is 28% which is more than double that of the National prevalence of about 12%. The Committee notes that as per the International Agency for Research on Cancer, alcohol is a confirmed cancer causing substance and the risk becomes higher when tobacco is consumed along with alcohol.**

**1.6.4 The Committee is of the firm view that there is an urgent need to disincentivize the consumption of tobacco and alcohol in the country. The Committee accordingly recommends the Government to formulate effective policies on alcohol and tobacco control. The Committee also notes that India has one of the lowest prices for tobacco products and there is a need to increase taxes on tobacco products. The Committee accordingly recommends the Government to raise taxes on tobacco and utilize the additional revenue gained for cancer prevention and awareness.**

**1.6.5 Attention of the Committee is also brought to the fact that more than 80% of tobacco consumption is in the form of chewing Tobacco with or without Areca Nut. These products are being aggressively marketed as mouth fresheners. The Committee accordingly recommends the Government to take measures to ban Gutka /Flavored Chewing tobacco/Flavored Areca (Pan Masala) and prohibit direct and indirect advertisements of Pan Masala.**

**1.6.6 Taking into consideration that oral cancer being the highest contributor to the total cancer cases, the Committee observes that there is a need to implement the provisions of Cigarettes and Other Tobacco Products Act 2003 (COTPA) more universally. The Committee notes that COTPA is the principal anti - tobacco law in India that encompasses a ban on smoking in public places, advertising and sponsorship, sales to minors, and warnings on packs. The Committee further notes that India's National Health Policy 2017 has set out to achieve a relative reduction in the prevalence of current tobacco use by 30% in 2025. The Committee believes to achieve the SDG target, the Ministry must take effective measures to contain the sale of Tobacco products. The Committee recommends the Government to abolish designated smoking areas in airports, hotels, and restaurants and encourage a smoke free policy in organizations. The Committee further recommends the Government to prohibit single stick sales of cigarettes and lay stringent penalties and fines on offenders.**

**1.6.7 The Committee finds that the most common cancers like the oral cancer, breast and cervix cancer in women can be prevented and can be handled in a better way if they**

are detected early. However, lack of awareness and poor screening facilities delay the diagnosis and the cancer is detected at a fairly advanced stage. The Committee accordingly recommends setting up a robust screening mechanism at each level so that with early detection the cancer is cured completely.

### Incidence of Age Adjusted Cancer Rates in Urban and Rural Area

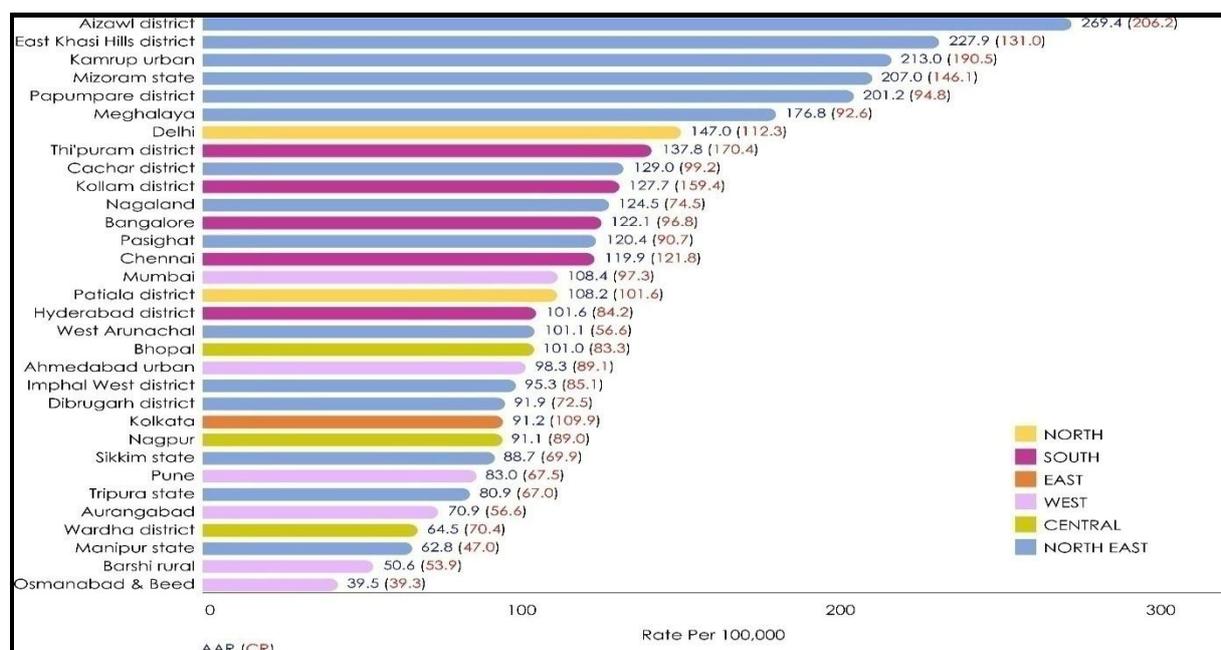
1.7 Highlighting the trends over time in Age Adjusted Rate with the details of Annual Percent Change (APC) for the selected PBCRs, the Ministry furnished the following information:-

PBCR (Year)	All sites – Males	All sites - Females
Bangalore (1982-2014)	0.8*	0.8*
Mumbai (1982-2015)	-0.5*	0.1
Chennai (1982-2016)	0.9*	0.3*
Delhi (1988-2014)	0.9*	0.0
Bhopal (1988-2015)	0.1	0.7*
Barshi Rural (1988-2016)	0.3	0.5*

\*Represents statistically significant APC ( $p < 0.05$ ) from zero

1.7.2 Informing about the overall comparison of rates of cancer data collected by registries, the Ministry pointed out high occurrence of cancer in most urban registries while lower rates of cancer are found in rural areas of Barshi, semi urban areas of Wardha and rural areas of North Eastern States (where the registry covers entire state). Comparison of Age Adjusted Incidence Rates (AARs) of all Population Based Cancer Registries (PBCRs) is graphically represented as follows:

### Comparison of Age Adjusted Incidence Rates (AARs) of all PBCRs ALL SITES (ICD-10: C00-C97) Males



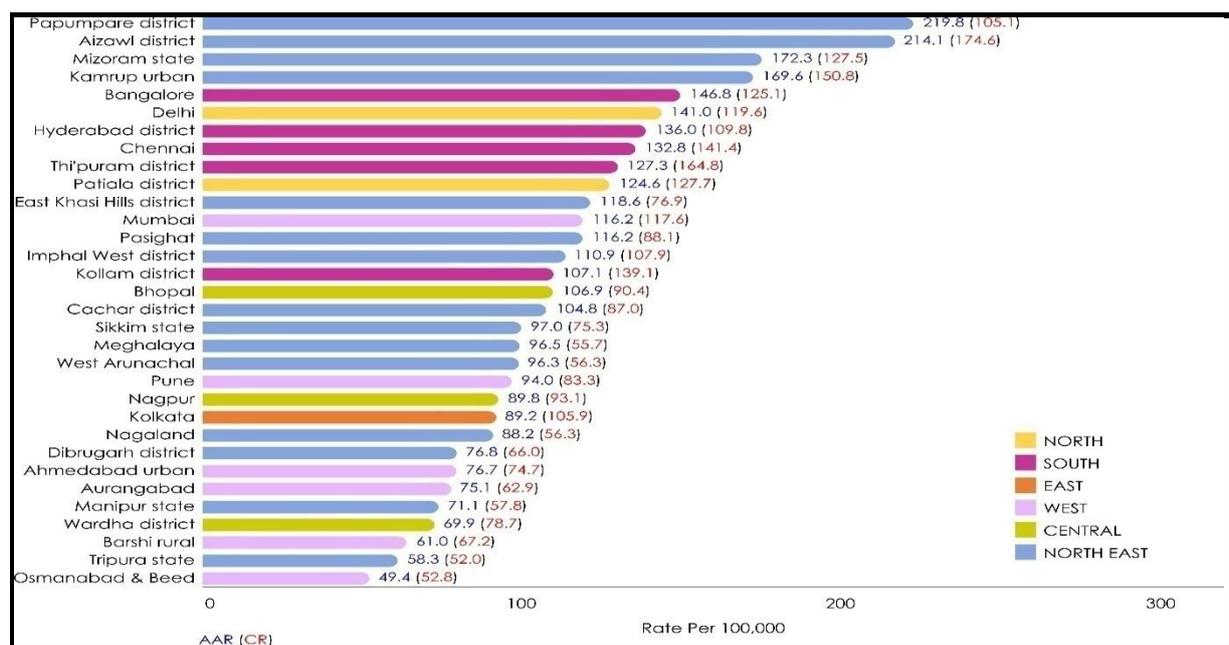
(Reference: Report of National Cancer Registry Programme 2020, Bengaluru)

1.7.3 The Committee is given to understand that a Population-Based Cancer Registry (PBCRs) collects data on all incidences of cancer cases from multiple sources in a geographically defined population. Population Based Cancer Registries (PBCRs) provide age specific cancer incidence rates which helps in estimating the risk of the particular population in developing Cancer. The Committee is further given to understand that Incidence refers to the number of new cases of a specific disease within a particular period and can be expressed as a risk or an incidence rate. The ‘crude incidence rate’ is expressed in terms of the number of new cases per 1,00,000 population per year. The Committee notes that ‘age-adjusted incidence rate’ is the rate after making statistical adjustments in the age factor, i.e a statistical process applied to rates of disease, death, or other health outcomes which allows communities with different age structure to be compared. The Committee further notes that north eastern region has the highest caseload of cancer in India.

1.7.4 The Committee observes that in Males, the six north eastern registries of Aizwal district, East Khasi Hills district, Kamrup Urban, Mizoram State, Papumpare district and Meghalaya have the Highest Age Adjusted Incidence Rates among all the PBCRs in the country. The Committee also observes that Aizwal district has the highest age-incidence rate of cancers among males which is 269.4 cases per 1,00,000 Males whereas the age-incidence rate of cancers among Males in Delhi is 147. The Committee notes that the highest incidence of cancer in India has been reported in the North Eastern region. In the southern region, Thiruvananthapuram has the highest AAR which is 137.8 cases per 1,00,000 Males followed by Kollam district which is 127.7 cases per 1,00,000 Males. In the western region, Mumbai occupies the top position with an AAR of 108.4 followed by Ahmedabad Urban with an AAR of 98.3. With 101 cases per 1,00,000 males, Bhopal has the highest AAR in the central region, followed by Nagpur with an AAR of 91.1., Kolkata has the highest age-incidence rate of cancers among males which is 91.2 cases per 1,00,000 males among all the eastern region registries.

### Comparison of Age Adjusted Incidence Rates (AARs) of all PBCRs

#### ALL SITES (ICD-10: C00-C97) Female



(Reference: Report of National Cancer Registry Programme 2020, Bengaluru)

1.7.5 The Committee notes that in Females, the four North Eastern registry areas of Papumpare district, Aizwal district, Mizoram State and Kamrup Urban had the highest AAR among all the PBCRs. Papumpare with 219.8 cases per 1,00,000 females is closely followed by Aizwal district with an AAR of 214.1. Among the registries in the southern region, Bangalore has the highest AAR of 146.8 followed by Hyderabad district with an AAR of 136. Delhi has the highest AAR with 141 cases per 1,00,000 Females in the north. In the west, Mumbai occupies the top position with 116.2 cases per 1,00,000 Females which is followed by Pune with AAR of 94. Bhopal with AAR of 106.9 has the highest AAR in the Central region. Kolkata has the highest AAR of 89.2 among all the registries in the eastern region.

**1.7.6 Keeping into account statistical interpretation of Comparative Age Adjusted Incidence Rates (AARs) of all PBCRs amongst men and women, the Committee recommends the Cancer Research Institutes to undertake Research Projects to understand the causative factors of gender specific cancer at specific site and come out with key solution to causation-continuum of cancer on cancer treatment.**

1.7.7 The Committee has been informed that the age-adjusted incidence rate in rural India is half of that of urban India. However, the burden of cancer in rural Indian settings is higher due to high percentage of rural population. As per the Population Based Cancer Registry (PBCR) of ICMR, the incidence of cancer is more or less stable since 1981. In developed countries incidence of cancer varies from 400-500 per lakh of population. In India, the incidence of Cancer in male is as low as 40 per lakh of population in Osmanabad & Beed district to as high as 270 per lakh of population in Aizawl district. Similarly, in case of female, it is as low as 50 per lakh of population in Osmanabad & Beed district to as high as 220 per lakh of population in Papumpare District of Arunachal Pradesh. The average incidence of cancer in India varies from 70-140 per lakh of population, whereas Aizawl District (Mizoram State), Kamrup Urban District (Assam) East Khasi Hills District (Meghalaya), Papumpare District (Arunachal Pradesh) is above 210 per lakh of population in case of male and above 170 per lakh of population in case of female.

**Comparative Mortality: Incidence ratio in the country**

1.8 As per the ICMR’s cancer registry report “Report of National Cancer Registry Programme 2020”, the number of incidences & mortalities of cancer cases by 28 PBCRs is as follows:

SL NO	Registry	Male			Female			Both Sexes
		Incidence	Mortality	M / I %	Incidence	Mortality	M / I %	M/I %
<b>NORTH</b>								
1	Delhi* (2012-2014)	31032	4691	15.1	29065	3613	12.4	13.8
2	Patiala District* (2012-2016)	5394	1635	30.3	6077	1451	23.9	26.9
<b>SOUTH</b>								
3	Hyderabad District* (2014-2016)	5143	758	14.7	6453	582	9.0	11.6
4	Kollam District* (2012-2016)	9930	5253	52.9	9780	3629	37.1	45.1
5	Thi'puram District (2012-2016)	13506	5724	42.4	14327	4567	31.9	37.0
6	Bangalore* (2012-2014)	13221	4529	34.3	15828	4335	27.4	30.5
7	Chennai (2012-2016)	14468	4312	29.8	16803	3626	21.6	25.4

EAST								
8	Kolkata (2012-2015)	10186	4270	41.9	9151	3309	36.2	39.2
WEST								
9	Ahmedabad Urban (2012-2016)	14579	3997	27.4	11025	2421	22.0	25.1
10	Aurangabad (2012-2016)	1923	331	17.2	2001	226	11.3	14.2
11	Osmanabad & Beed District (2012-2015)	3635	967	26.6	4467	969	21.7	23.9
12	Barshi Rural (2012-2016)	726	522	71.9	813	512	63.0	67.2
13	Mumbai* (2012-2015)	26256	15696	59.8	27458	14388	52.4	56.0
14	Pune (2012-2016)	9687	4039	41.7	10818	4006	37.0	39.2
CENTRAL								
15	Wardha District* (2012-2016)	2389	1574	65.9	2537	1344	53.0	59.2
16	Bhopal (2012-2015)	3567	1318	36.9	3589	1014	28.3	32.6
17	Nagpur (2012-2016)	5952	1390	23.4	6047	1176	19.4	21.4
NORTH EAST								
18	Manipur State (2012-2016)	3702	1155	31.2	4500	1008	22.4	26.4
	Imphal West District (2012-2016)	1137	349	30.7	1500	322	21.5	25.4
19	Mizoram State (2012-2016)	4323	2492	57.6	3736	1566	41.9	50.4
	Aizawl District (2012-2016)	2180	1216	55.8	1900	757	39.8	48.4
20	Sikkim State* (2012-2016)	1172	603	51.5	1131	513	45.4	48.5
21	Tripura State (2012-2016)	6559	3682	56.1	4914	2395	48.7	53.0
22	West Arunachal (2012-2016)	1222	321	26.3	1171	202	17.3	21.9
	Papumpare District (2012-2016)	472	118	25.0	528	79	15.0	19.7
23	Meghalaya (2012-2016)	4688	1848	39.4	2832	1098	38.8	39.2
	East Khasi Hills District (2012-2016)	2884	1169	40.5	1729	744	43.0	41.5
24	Nagaland (2012-2016)	1403	298	21.2	992	119	12.0	17.4
25	Pasighat (2012-2016)	321	74	23.1	303	52	17.2	20.2
26	Cachar District* (2012-2016)	4663	895	19.2	3943	617	15.6	17.6
27	Dibrugarh District (2012-2016)	2535	669	26.4	2238	396	17.7	22.3
28	Kamrup Urban* (2012-2016)	6223	1913	30.7	4790	1002	20.9	26.5

(Reference: Report of National Cancer Registry Programme 2020, Bengaluru)

**Note: ICMR-NCDIR collects information on deaths through Population Based Cancer Registries. The numbers are likely to be inadequate due to incomplete recording of cause of death information.**

1.8.1 The Committee is given to understand that the Mortality Incidence Percent (M/I%) ranged from 14.7% to 71.9% in Males and 9.0% to 63.0% in Females. The Committee further notes that the highest M/I% was in the western region in Barshi Rural where M/I% was 71.9% in Males and 63% in Females. Hyderabad district had the lowest Mortality Incidence Percent in Males (14.7%) as well as Females (9.0%).

**1.8.2 The Committee also notes that as per the Report on Medical Certification of Cause of Death 2020, medically certified deaths account for 22.5 per cent of total registered deaths at National level (including figures of 34 States/UTs). The Committee notes that lack of a well defined system to log the cancer deaths poses a big hurdle in the collection of accurate cancer mortality data. The Committee emphasizes that incomplete and inaccurate account of death may further lead to a poor database on the mortality data**

of different types of cancer. The Committee, therefore, recommends that there is an urgent need to develop a better system of reporting the causes of death so that cancer mortality can be projected in a better manner.

**1.8.3** The Committee expresses concern over the alarming trend of increase in patients diagnosed with cancer, deaths due to cancer that is expected to rise from approximately 8 lakhs in 2018 to about 13 lakhs in 2035. The Committee notes the submission that the mortality: incidence ratio of 0.68 in India is higher than that in very high human development index (HDI) countries (0.38) and high HDI countries (0.57). Although, such disparity is because of over diagnosis in more developed countries, however, the Committee emphasizes that it could be due to the unequal distribution of and lack of access to health care resources across India.

### **Major geographical variation in the incidence of cancer**

1.9 The Committee has been apprised of geographical variation in the incidence of cancers. Cancers of Mouth and Tongue has been observed in Cancer Registries of Western and Central India. The occurrence of mouth cancers is high in areas covered by registry in Ahmedabad (Gujarat) among men while Bhopal (Madhya Pradesh) shows tongue cancers ranking high in women. The state of Maharashtra has also shown these cancers ranking high in both genders while they were much lower in adjacent geographical areas. Similar preponderance of these cancers is seen in state of Meghalaya of the country. Nasopharyngeal cancer has slightly more occurrence in the State of Nagaland. It was leading site of cancer for males and featuring in top five sites in females which was not seen in any other part of the country

1.9.1 While the Cancers of Gall Bladder is increasingly traced in Northern and Eastern regions. Earlier records have drawn our attention to a relatively high frequency of gall bladder cancer in a geographical band of high-risk, extending from Punjab in the west, through to West Bengal in the east and on into the northeast. As per the recent report, cities in Northern river plains (Delhi) and those along the river Brahmaputra (Kamrup) have recorded higher numbers of Gall Bladder cancers.

1.9.2 Especially among women, cancer of the thyroid show relatively higher incidence in the north-eastern states. Comparatively, high incidence of cancer of thyroid is recorded from the south-western coastal tip of the country, as evident by the data from districts of Thiruvananthapuram and Kollam. The cancer registries of Mizoram, Sikkim, Meghalaya, Arunachal Pradesh, Nagaland and Assam (Dibrugarh, Cachar and Kamrup) in the North-eastern states show clear geographic correlation with stomach and oesophageal cancers (in both genders).

**1.9.3** The Committee takes into account the major geographical variation in the incidence of Cancer cases and feels that the Government should encourage region based cancer research projects to understand the causation of specific cancer in a specific region and come out with the conclusion and research outcome for cancer treatment. Similarly, cancer research projects should also cover studies on differential occurrence of cancer in rural and urban areas and provide key solutions to the increasing incidence of cancer cases in rural areas.

1.9.4 As regards the Cancers in Adolescents and Young Adults (AYA), the Committee has been informed that an estimated 22 cases per 100,000 males 29.2 per 100,000 females in the 15 to 39 years age group were reported for the period 2012-2016. The relative proportion of

AYA cancers to all cancers was the highest for males in Nagpur (17.7%) and females in Nagaland (26.9%).

1.9.5 Apprising about the institutional arrangement of Cancer treatment, the Ministry of Health and Family Welfare maintained that the Cancer is being diagnosed and treated at various levels in the Govt. Health Care Delivery System consisting of Subcentre, Primary Health Centre (PHC), Community Health Centre (CHC), District Hospital besides medical colleges and tertiary care institutions. Financial and technical support is provided upto the District level. Even though health and hospitals are a State subject, the Central Govt supplements the efforts of state govt in preventing and controlling cancer. To enhance the facilities at tertiary level, the Central Govt is implementing the scheme of strengthening of Tertiary Care for Cancer Centre (TCCC). Under this scheme, 39 SCIs/TCCCs have been approved. Under the aegis of Pradhan Manti Swasthya Suraksha Yojana (PMSSY), setting up of 22 new AIIMS and upgradation of 75 Govt. Medical Colleges has been taken up. Cancer treatment facility has been envisaged in all the 22 AIIMS. Out of these, six AIIMS at Bhopal, Bhubaneswar, Jodhpur, Patna, Raipur and Rishikesh are already functional where cancer treatment facility is operational. These AIIMS have been provided with state-of-art diagnostic, medical and surgical care facilities. Cancer treatment facilities have also been created / planned in 13 State Govt. Medical Colleges which have been taken up for upgradation under PMSSY.

1.9.6 The Ministry *vide* its background note informed the Committee that the National Programme for Prevention and Control of Cancer Diabetes Cardiovascular Diseases and Stroke (NPCDCS), focuses on three most common types of cancer namely Oral cancer, Breast cancer and Cervical cancer. The Programme aims at strengthening infrastructure, human resource development, health promotion, early diagnosis, management and referral. For safeguarding the beneficiaries from catastrophic expenditure of cancer treatment, Pradhan Mantri Jan Arogya Yojana (PMJAY) is being implemented. Health insurance cover of Rs. 5 lakhs per family per year for secondary or tertiary care hospitalisation to over Rs.10.74cr. poor and vulnerable families is being provided. The treatment of cancer in Govt. institutions is either free or subsidised. Poor patients also get financial assistance under the umbrella scheme of Rashtriya Arogya Nidhi (RAN). Another novel initiative, Affordable Medicines and Reliable Implants for Treatment (AMRIT) and Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana (PMBJP) aim at providing affordable life saving medicines and medical disposables to patients suffering from cancer.

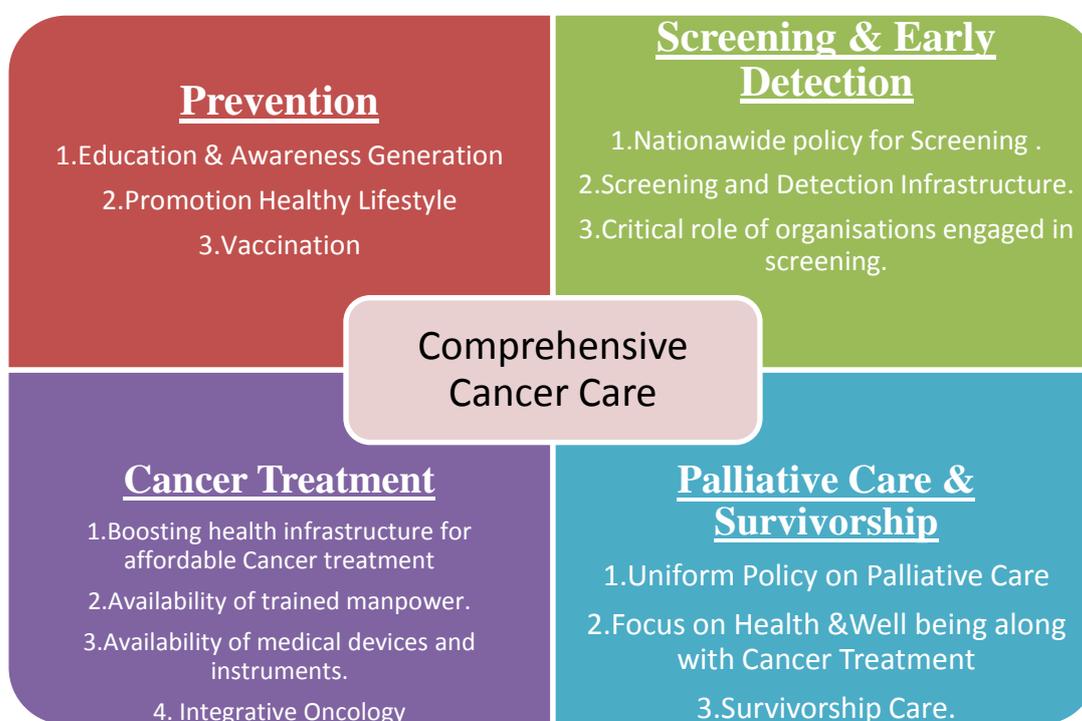
## CHAPTER-II

### PREVENTION, SCREENING, EARLY DETECTION AND DIAGNOSIS OF CANCER CASES

2.1 The cancer control continuum aptly describes various stages of cancer care and management, these are cancer prevention, screening, early detection, diagnosis, treatment, palliative care and survivorship. The cancer control continuum is a useful framework to view the strength, weaknesses, progress, and priorities of a country with regards to Cancer care. It helps the policy makers to identify areas which need focused attention, aspects where more resources are required to be enhanced and gaps which demand collaboration with others to have the desired impact.

2.1.1 According to WHO, screening and early detection of cancer greatly increases the chances for successful treatment as it focuses on detecting symptomatic patients as early as possible and testing healthy individuals to identify those having cancers before any symptoms appear. In a country like India where health care is generally expensive while often failing to deliver the level of desired/recommended care, the situation turns grimmer when the disease is Cancer. In India where the policy makers deal with limited resources, cancer control continuum framework presents the case for more focus on prevention, screening and early detection. Such emphasis on prevention, screening and early detection may reduce the cancer burden on the healthcare infrastructure of the country in the coming years and thus provide time and free more resource to strengthen the entire gamut of cancer care infrastructure not only at the tertiary level but also at the secondary and the primary level.

#### Facets of Cancer Care in India



## CANCER PREVENTION

2.2 As per WHO, Cancer prevention is the action taken to lower the risk of getting cancer. This can include maintaining a healthy lifestyle, avoiding exposure to known cancer-causing substances, and taking medicines or vaccines that can prevent cancer from developing.

2.2.1 In our country the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS), focuses on three most common types of cancer namely Oral cancer, Breast cancer and Cervical cancer. The Programme aims at strengthening infrastructure, human resource development, health promotion, early diagnosis, management and referral.

2.2.2 Population based prevention and control, screening and management initiative for common NCDs (Diabetes, Hypertension and common cancers viz. Oral, Breast and Cervical Cancer) is being implemented as part of comprehensive primary health care under National Health Mission (NHM). Population Based Screening can help in better management of diseases by the way of early stage of detection, follow up and treatment adherence. Training Modules have been developed for training of various categories of health staff viz. Nurses, ANMs, ASHAs and Medical Officers. Awareness for prevention of cancer and early detection of cancer is being carried out at all levels through NCD Clinics at Districts & CHC levels. In addition, the print media, audio- visuals and the social media such as tweets is also utilized for the purpose. ICMR's National Institute of Cancer Prevention & Research has designed a portal on "India against Cancer" that provides information on the leading cancers in India with a major focus on awareness, prevention and treatment of these cancers. The portal focuses on information for the general public and patients.

**2.2.3 The Committee recommends that the Government pays attention to low-hanging fruits by stressing the need for cancer prevention and screening. While cancer prevention measures like increasing awareness amongst masses can make the public at large more aware and allay fears regarding cancer, adequate and effectively implemented screening measures would result in early detection of potential cancer cases, thereby decreasing the load on existing health infrastructure and also saving the family/patient from financial hardships. Appreciating the importance of screening the Committee recommends the Government to formulate a nationwide policy on screening, and as in the case of Covid-19 vaccination, the Government can implement compulsory cancer screening measures on certain age groups, like 30+ age group population.**

### **Vaccination against Human Papilloma Virus (HPV)**

2.3 The committee has been given to understand that vaccination against Human Papilloma Virus (HPV) for girls in the eligible age group can substantially reduce the cervical cancer incidence to near elimination levels in the foreseeable future. This will also protect the next generation of women from this cancer by building up successive cohorts of women at low risk for HPV infection. Australia, which was the first country to introduce universal HPV vaccination and routine screening by HPV testing, has since 2007 seen a 92% decline in the prevalence of infection of vaccine targeted HPV types in females aged 18-25 years. Pre-cancerous cervical lesions also halved in young women aged 20-24 years in Australia between 2006 and June 2017. This reflects impact of universal HPV vaccination in prevention and more importantly offsetting the economic burden associated with the treatment and management of HPV related cancers.

2.3.1 Replying to a query on preventive cancer care-the possibility of implementing vaccination, the TATA Memorial Hospital, Mumbai during the study tour of the Committee to Mumbai on 28<sup>th</sup> April, 2022, apprised the Committee that the incidence of cervical cancer is coming down in all Indian cancer registries, including rural registries. The HPV vaccine results have yet to prove an effect in reducing cervical cancer mortality convincingly. HPV vaccine given to young girls is likely to impact if at all, cervical cancer after several decades, by which time the incidence all over India would already be very low, given the current trends. Hence, TMC does not recommend HPV vaccination as a strategy to control cervical cancer in India. The institute informed the Committee that most cost-effective and sustainable solution is the accessibility to hygienic toilets and bathing for all women. For the high-risk population, visual examination with Acetic Acid by the health workers is a simple, evidence based tool for screening.

**2.3.2 The Committee has been given to understand that certain common cancers viz. cervical, vaginal, vulvar as well as genital warts which are mostly associated with Human Papillomavirus (HPV) infection can be prevented with vaccination. The Committee observes that vaccination for Cancer like the disease itself is associated with stigma and fear and hence it is necessary to raise awareness for both primary care physicians and patients on early warning signs/ symptoms of Cervical Cancer. The Committee feels that there is still lack of a consensus for using HPV vaccine to prevent Cervical cancer. Taking into account the fact that the vaccine has proved effective in preventing Cervical cancer in countries like Australia, the Committee recommends the Ministry to authorize few more projects to study the efficacy of the vaccine on Indian women, and if satisfactory results are achieved, the Government may consider including the HPV vaccine in the vaccination programme of India.**

**2.3.3 The Committee further believes that intensive information, education and communication (IEC) activities are required to sensitize the people about the danger of the Cancer disease and the advantages associated with its early detection through screening. The Committee recommends that to increase the awareness, the Government should organize block-level camps, programmes at Schools, Colleges, universities and also start mass radio and media campaigns (like it did to eradicate TB, polio, etc) for spreading cancer awareness in the general population regarding (i) preventive care for cancer (ii) symptoms of common cancer and reach out to the affected people at early stages in order to save the human and financial resources of the country. Additionally to give impetus to the awareness about Cancer, the Government should take following measures:**

- i. Information dissemination through village panchayat members, primary health centers staffs, posters and banners in bank and post office branches. Also, local political leaders, religious leaders and other social groups should be sensitized and their help should be taken to spread awareness and motivate the population to undergo screening.**
- ii. Local Cable network shall also be used for creating awareness. Such networks can air awareness based programmes using local actors to sensitize people about Cancer.**
- iii. School Students and the teachers shall be made aware about Cancer, and then camps should be organized under NSS (National Service Scheme) where these children should increase awareness about Cancer, need for screening in nearby villages and settlements.**

- iv. **The Resident Medical Officers (RMOs), Ayurvedic MOs and Homeopathic MOs should also be engaged to generate awareness about the cancer prevention and importance of screening.**
- v. **Health workers like ASHA/Health/Anganavadi workers should be trained and provided with IEC materials so that they can interact with local population effectively.**
- vi. **The Government should start a help line number integrated with telemedicine (eSanjeevani-app of government) for cancer awareness, in addition to the awareness, the helpline shall be able to guide patients on next steps of care/ treatment facilities in their vicinity and how to avail the same.**

**2.3.4 The Committee notes that in India tobacco use in different forms accounts for nearly 50 % of all cancers, these are called tobacco related cancers, so these cancers are preventable. The Committee expresses its concern to note the fact that while thousands of crores are spent by both Central and State Governments on treatment of Cancer, however, the desired focus is not given to its root cause i.e. tobacco consumption. The Committee has been given to understand that majority of tobacco addicts start in their teens. Therefore, the Committee recommends the Government to focus campaign against tobacco consumption by youth and since the "quit-rate" in India is very low, the Government should formulate strategies to stop the teen-population from falling prey to the tobacco addiction.**

**2.3.5 The Committee notes that another preventable cancer is Cervical cancer, which is the second most frequent cancer among women between 15 and 44 years of age with a high death ratio in India. The Committee has been given to understand that the Drugs Controller General of India (DCGI) recently granted market authorisation to Serum Institute of India (SII) to manufacture indigenously-developed India's first Quadrivalent Human Papillomavirus vaccine (qHPV) against cervical cancer.**

**2.3.6 Regarding lifestyle practices that enhance risk of cancer, the Committee observes that the Government should work towards preventing obesity in youth by increasing the levels of physical activity. The Committee recommends that this can be done by two ways: (a) better urban and rural planning, making sure that physical activities are encouraged by way of dedicated jogging, walking and cycling tracks; Yoga should be promoted and made mandatory in schools for well being of children; (b) dissuade children from consuming ultra-processed foods and drinks which lack nutrients by ensuring Front of Packet Labels (FOPL) which is easily seen and understood; (c) increase in the taxes on junk food and sugary drinks which is actually creating an epidemic of obesity, especially among young children. The Committee has been given to understand that improper methods used for food preservation is one of the main reasons why the cancer incidence in the North-East India is much higher than the rest of the country. The Committee, therefore, recommends that the Government should promote better hygiene and encourage people to avoid foods (processed meat) that have been processed and preserved by employing techniques of salting, smoking or curing as consumption of even small amounts of these food increases the risk of cancer.**

### **Challenges in Cancer Prevention**

**2.4 The AIIMS, Raipur, submitted the below major challenges being faced in the cancer prevention:-**

- i. The lack of awareness, misinformation, lack of trust in medical establishments, having to travel far to access care, lack of involvement of the patient in treatment-related decision-making and financial hardships to support the direct and indirect costs of cancer care often contributed to the delays in getting treated for cancer.
- ii. In India, many of the prevention programmes assessed have been estimated to be cost-effective in the long run but do not have any organised national cancer screening programmes.
- iii. The existing approaches in India for screening of cervical cancer include exfoliative cytology, visual inspection with acetic acid, and human papillomavirus but the human papillomavirus test is mainly available through major private centres.
- iv. In India, caste-based politics, demography and geography are some of the factors that lead to inequity in the distribution of resources.
- v. The epidemiological transition occurred from the high prevalence of infectious diseases associated with high mortality (especially in infants) to an increasing burden of non-communicable diseases in adults.
- vi. Most of the people with cancer first present in the private sector, the reason behind this is that there is low trust in public cancer care services.
- vii. The Indian healthcare system is characterized by high rates of privatization since the 1960s, with low penetration of voluntary and social health insurance schemes, and a high frequency of out-of-pocket payments, with only around 15% of the country's population covered by some degree of health insurance.
- viii. In India, breast cancer clinical examination is recommended as a cost-effective approach, by contrast with high-income countries where mammography is the gold standard, since neither the necessary machines nor trained manpower to read the mammograms is available in India.
- ix. Deficits such as illiteracy, inadequate and inaccessible care, inappropriate initial treatment by traditional healers, myths and stigma surrounding cancer and its treatment, and general misconceptions among family members, society, and even the administrators of general hospitals regarding the prognosis of cancer have negative effects on affordable cancer treatment.

**2.4.1 The Committee takes cognizance of the various challenges being faced in the prevention of Cancer and agrees with the fact that most of the people with cancer, prefer approaching the private sector, due to low trust and inadequate public cancer care services. The Committee recommends the Ministry to work actively towards bridging the trust deficit in public health institutions by improving the overall healthcare infrastructure of the public health facilities. The Committee feels that the need of the hour is to upgrade existing cancer care facilities and expand the same to the areas which have high incidence of cancer cases especially in the North Eastern Region so that the patients get access to quality and cost-effective cancer care.**

## **CANCER SCREENING & EARLY DETECTION**

2.5 The Department of Health Research submitted before the Committee that screening of common NCDs including common cancers (viz. oral, breast and cervical) is also an integral part of service delivery under Ayushman Bharat- Health and Wellness Centres. A total of 80,010 HWCs have been operationalized out of the target of 1.5 lakh throughout India. The number of persons screened so far through Health and Wellness Centres (HWCs) includes

771.20 lakh for oral cancer, 386.10 lakhs for breast cancer and 262.49 lakh for cervical cancers.

2.5.1 As per the Operational Framework on Management of Common Cancers by Ministry of Health and Family Welfare 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 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 year. The Ministry of Health and Family Welfare in its submission to the Committee has apprised that the growing burden of Cancer in India is a serious concern, as it leads to not only high numbers of premature deaths but also impacts the quality of life. Cancer can affect any part of the human body, though in India, highest number of lives lost is due to oral cancer caused by tobacco followed by cancer of the lung, oesophagus and stomach. Amongst women, breast cancer and cervical cancer is most common. It is worth noting that cancers like that of breast, cervix and oral are preventable if diagnosed early. In order to address this serious issue, the government's strategy is to focus at interventions ranging from early screening and detection to facilitating affordable and comprehensive management and care of cancer patients.

2.5.2 Operational Framework on Management of Common Cancers states that 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 India. 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.

2.5.3 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 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 researched and accepted as a potential alternative to cytology in low resource settings.

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.

**2.5.4 The Committee notes that the screening of common Cancer under NPCDCS program is mostly opportunistic, which is volunteer based, and thus lacks the follow up strategy for further investigation and treatment of those who are screened positive, due to this the results may not be evaluated any further. Moreover, only three common Cancers - oral, cervical and breast are focused under the NPCDCS since inception of the program. With enough evidence with respect to increase in burden of other Cancers, the Government must consider inclusion of other prevalent cancer types under the program. The Committee further notes that while many cancers are preventable not all cancers are preventable, being age related, i.e. breast cancer, bowel cancer, prostate cancer etc. Hence strategy in these cancers is not prevention but early diagnosis through screening programs and their management. The Committee is of the opinion that there is an imminent need for a Central Government sponsored national screening programs for cancer in India.**

**2.5.5 The Committee recommends that from the present policy of opportunity based screening, the Government should formulate a scheme to start a country wide population based screening at the PHC level under the NHM (National Health Mission). The Committee is of the considered view that for screening programmes to be easily accessible, particularly for women and other vulnerable groups, they need to be decentralized to grass root level. The Committee recommends that each PHC should take up the responsibility of screening people who reside in its catchment area. The Medical Officer, Public Health Nurse, Health Assistants, and Health Workers should be encouraged to take a lead in the screening camps organized under the scheme. Furthermore, according to convenience of the PHC, one-two days in a week should be designated for Cancer Screening. The days for screening should be prominently displayed through billboards near the PHC and other locations of high population density. The Committee feels that proactive Government efforts are required to contain the growing trend of cancer. Accordingly, the Committee recommends that the Central Government in tandem with State Governments should commence mobile detection programmes with vehicles equipped with colonoscopy, mouth inspection, uterine-cervix tools & instruments, and other laboratory facilities in every district of the country. The Government must also work towards reaching the needy as has been done in Polio vaccination and start home screening for detection of breast, cervical and oral cancer. The Government should also develop mechanisms to link the screening programmes to cancer registries across the country, for better management of cases at early stages and data containing information on incidence and prevalence of cancer and related morbidities should be utilized in future cancer control programmes.**

**2.5.6 The Committee feels that in order to address the issue of prevention of all sorts of Cancer, mandatory screening of people of certain age groups for example 30+ age group population may be done every year. Early detection and timely diagnosis reduces the cost of care and mortality significantly. Therefore the trumpet call is to take all the measures for mass level cancer screening. People, who avail of screening for cancer should get atleast marginal concessions in the insurance, so that provision of concession acts as an incentive for citizens to participate in the screening as per government guidelines.**

## Organization of Referral and Treatment Services

2.6 Operational Framework: Management of Common Cancers proposes paradigm shift in the Operational Guidelines (OGs) for Screening. It says that screening programmes should be brought closer to the community but establishing a balance between skill, 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 identify suspicious lesions, service providers should:

- (i) 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.
- (ii) Undertake appropriate and timely follow-up of those with positive or abnormal results so that they access the services required.
- (iii) Support and enable referral of confirmed cases to cancer treatment services.

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

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

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

2.6.3 Details of screening at each level as mentioned in Operational Framework: Management of Common Cancers is:-

For Screening for common cancers the first level screening is 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.

ANMs should be trained in visual examination of the oral cavity, clinical breast examination, visual inspection using Acetic Acid (VIA) for cervix cancer screening. Staff Nurses and Medical Officers at all facilities viz. PHC,CHC and DH should be trained in screening methods, so as to serve as mentors and trainers to the next lower level.

Training of 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. All CHCs in the district would be strengthened to provide confirmatory tests for those screened and suspected of abnormal test results. Colposcopes and ultrasound breast probes would have to be provided at CHC/DH level as appropriate to state concerned and depending on availability of a trained health staff.

Implementation of this programme would be through the regular health system, supported by the District NCD cell for planning, monitoring and reporting. 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.

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.

**2.6.4 The Committee acknowledges the detailed Operational Guidelines (OGs) for screening enlisted in "Operational Framework: Management of Common Cancers". The Committee recommends the Ministry to develop plan for the implementation of the framework. The Committee also recommends that screening programmes should be brought closer to the community by establishing the screening facilities in the PHCs and CHCs, also viable referral linkage to diagnosis and treatment centers at secondary or tertiary levels should also be ensured.**

## **CANCER DIAGNOSIS**

2.7 As per the memoranda submitted by Novartis Healthcare Private Limited, India has high burden of Cancer and the majority (75-80%) of the patients are diagnosed at an advanced stage<sup>3</sup> resulting in poor survival and high mortality. Hence it is imperative that early detection services (screening) should be kept functional at out-patient settings so that patients coming to hospitals with early signs and symptoms can be diagnosed (Confirmatory Diagnosis) as early as possible.

2.7.1 Cancer is an incredibly diverse disease, with different types of Cancer, arising in different organs with differing behavior resulting from the interplay of host, environment and micro environmental factors, making diagnosis the biggest complexity of the disease. Each Cancer is diagnosed with a combination of tests including advance diagnostic methodologies such as molecular biology, next-generation sequencing, Artificial Intelligence, advanced imaging, and radiation making the overall process, resource intensive and technical. Setting standard diagnostics protocol and exploring the inclusion of new diagnostic technology could make the Cancer management more precise, targeted, cost effective and efficient.

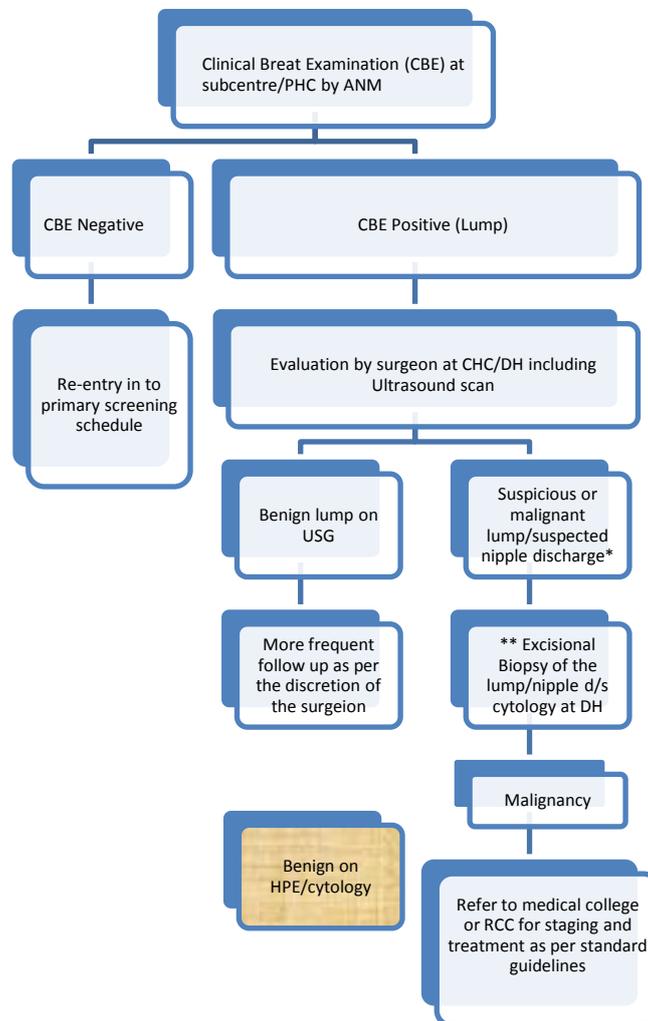
2.7.2 According to Operational Framework: Management of Common Cancers, only screening the population is not enough as the positive screening test results need to be given proper follow up and diagnosis of the disease is a must. For this objective, each screening site should be linked to facilities with diagnosis and treatment. Therefore, each individual screened positive at the screening sites 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/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.

2.7.3 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.

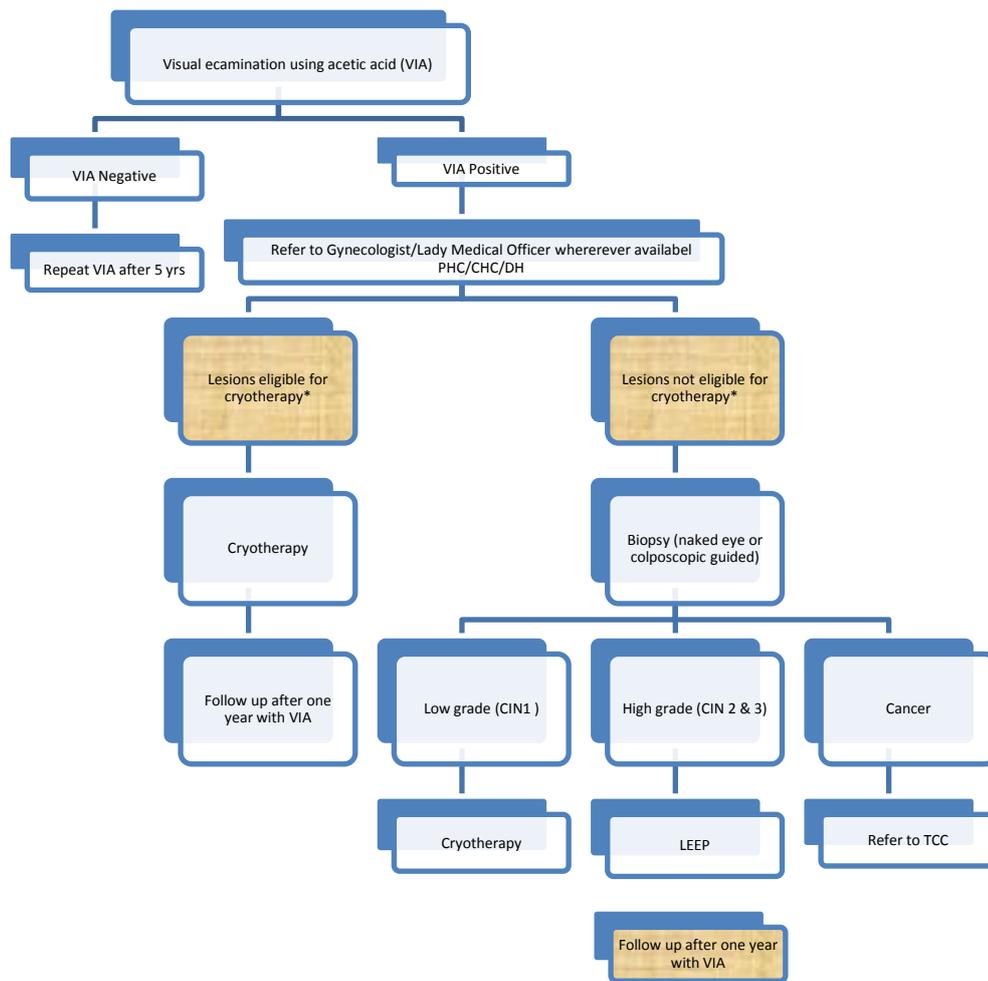
2.7.4 Cancer patients under treatment and their family/care-givers also need support. In addition to treatment facilities, states are encouraged to explore partnerships with organizations that provide community based palliative and rehabilitative care. States are also encouraged to create cancer support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

2.7.5 The Operational Framework: Management of Common Cancers proposes screening programmes for certain types of cancers:

### Screening and Diagnosis Algorithm for breast cancer



## Screening and Diagnosis Algorithm for Cervical Cancer



**Please Note:** The accuracy of VIA decreases in postmenopausal women. However, in facilities where there are no resources for Pap, women may be screened using VIA till 65 years of age.

### \*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:

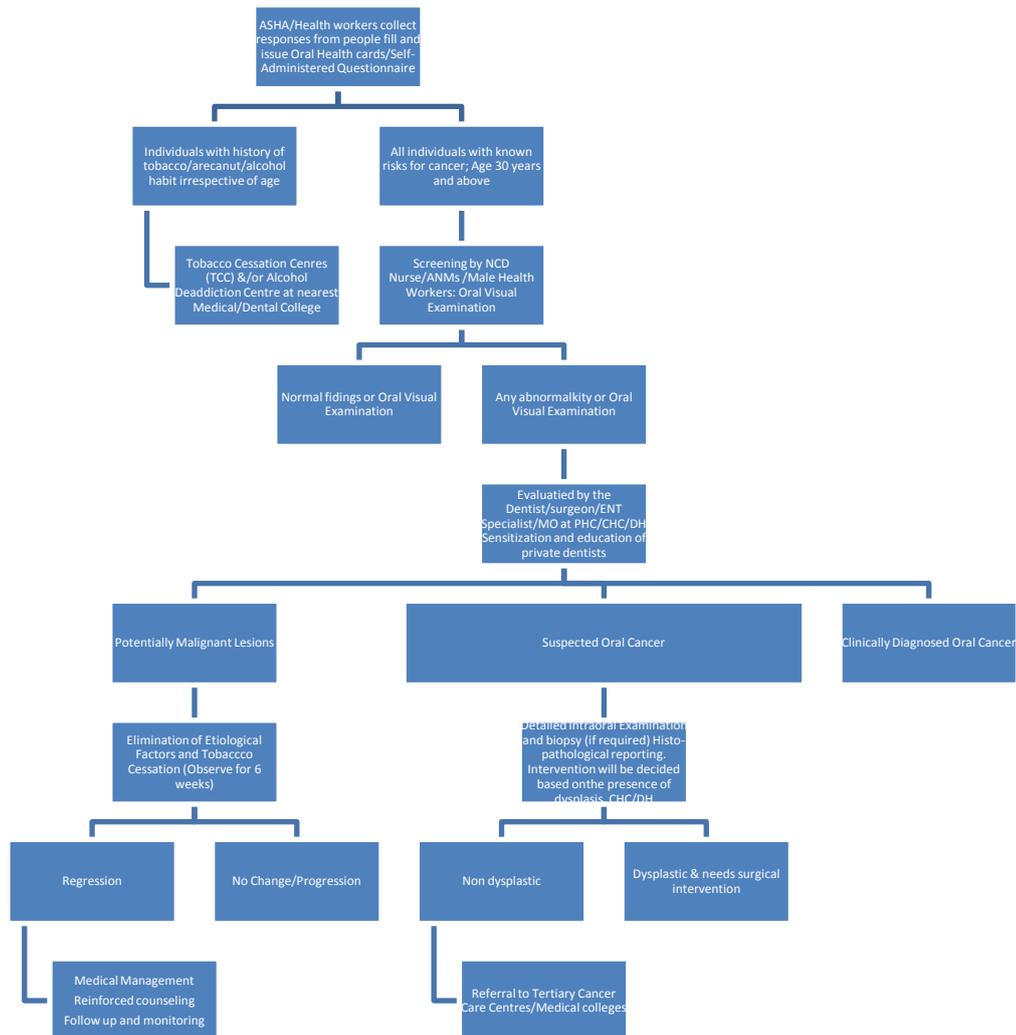
#### Symptoms:

1. Postcoital bleeding
2. Postmenopausal bleeding

#### Examination:

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

## Screening and Diagnosis Algorithm for oral cancer



**2.7.6** The Committee notes that each Cancer is diagnosed with a combination of tests including advance diagnostic methodologies such as molecular biology, next-generation sequencing, Artificial Intelligence, advanced imaging, and radiation making the overall process, resource intensive and technical. The Committee recommends the DoH&FW and ICMR to set up standard diagnostics protocol and explore the inclusion of new diagnostic technology as modern technology could make the Cancer management more precise, targeted, cost effective and efficient. The Committee is however concerned that the diagnostics procedures are very costly and due to lack of diagnostic facilities in the public hospitals, patients have to rely on private hospitals for testing where they are charged heavily. The Committee, therefore, recommends to cap diagnostic testing charges so as to give relief to the patients and this will also encourage the screened positive cases to turn up for diagnostic testing. The Committee further recommends the Ministry to do an assessment of diagnostic facilities in all District Hospitals (DHs) in the country and work towards establishing decentralized diagnostic testing network by establishing basic diagnostic facilities in all the District Hospitals (DHs) in the country, the Ministry should incorporate extensive coverage for diagnostic services under PMJAY.

## Human Resource Requirement

2.8 The Committee has been informed that the success of the Operational Framework is dependent on the requisite HR being in place at all levels. 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.

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

**2.8.1 The Committee appreciates the Ministry for developing a detailed "Operational Framework: Management of Common Cancers" enlisting the details of screening methods, diagnostic procedures and training requirements of the human resource involved. The Committee recommends the Ministry to develop plan for the implementation of the framework and ensure that the requisite number of healthcare personnel are appointed in PHCs, CHCs and DHs as early as possible. The Committee also recommends that the Ministry should develop certain indicators to ascertain the effectiveness and progress of the "Operational Framework" once it gets implemented. The Committee recommends adding relevant attributes/ indicators to large scale periodic surveys such as the National Family Health Survey (NFHS), National Sample Survey Organization (NSSO), District Level Household Surveys (DLHS) to assess the impact.**

### **Training Strategy**

2.9 The Operational Framework elaborates a cascade approach to training under which training would be provided to 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. 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.

2.9.1 Training would cover the following areas:

- (i) Understanding the concepts and operational details of the programme at all stages.
- (ii) Understanding cross linkages with existing programmes and skills in leveraging resources across programmes.
- (iii) Building skills and competences in skills for screening and for confirmatory tests for those who would be undertaking the procedures.
- (iv) Communication and counseling skills
- (v) Work flow processes at various levels
- (vi) Recording and Reporting
- (vii) Referrals and Follow up at community level

**2.9.2 The Committee observes that one major hurdle in successful early detection of cancer cases is lack of knowledge at the physician level about early signs of cancer. The Committee, therefore, strongly recommends that all Primary Care Physicians and frontline Healthcare workers to be trained for identification and detection of red flags for early diagnosis, further referral and follow up care management. A structured course including clear clinical pathways may be mandated to be taken on regular intervals. This will promote early diagnosis and treatment. The Committee recommends the Ministry to set up well-defined and established referral mechanisms so that patients are referred to the 'nearest and appropriate' diagnostic facility (including imaging, laboratory or molecular tests) for pathological confirmation and staging studies. This can help to augment capacities for early diagnosis by integration and coordination of all existing facilities in the country. The Committee recommends that to augment existing**

**facilities, private facilities should also be empanelled to provide easy access to patients to provide free/subsidized screening/diagnostics for cancer.**

#### **DHR-ICMR Advanced Medical Oncology Diagnostic Services (DIAMOnDS):**

2.10 Owing to India's increasing cancer burden and disparities in access to diagnostic and prognostic tests for cancer, DHR-ICMR Advanced Molecular Oncology Diagnostic Services (DIAMOnDS), a multi-centric study was initiated. This study aimed to set up zonal molecular oncopathology labs to provide basic, high-end advanced diagnostic services to cancer patients and research facilities for basic, translational, and clinical research. The diagnostic facilities are provided in twelve leading cancer hospitals across the country. This study was initially initiated for lung and breast cancers, wherein the biomarkers are available for these cancer patients. ICMR-NCDIR serves as a Data Management Centre for the DIAMOnDS centres with the objectives to facilitate data management for the project and to link the biomarkers in breast and lung cancer test results to the NCRP registries to improve cancer data for patient management and research.

#### **ICMR-India Cancer Research Consortium (Diagnostics):**

2.11 Considering the dire need for early diagnosis of cancer, under the aegis of diagnostics thematic area of ICMR-ICRC two projects are ongoing viz. (a) FloNamiR: A nano-hybrid array for quantitative estimation of lung cancer associated circulating cell-free micro RNAs aiming to develop a pragmatic, novel nano-hybrid array as a minimal-invasive approach for the targeted and amplification-free quantitative detection of the LC associated aberrantly expressed ccf-miRs in a pool of mRNAs using flow cytometry; (b) STAT3-HPV Flow-FISH: Development of innovative single molecule RNA (smRNA) detection, flow cytometry- based quantitative and diagnostic assay for detection of transcriptionally active high risk-HPV infections.

**2.11.1 The Committee understands that the screening followed by diagnostic programs for cancer require the assurance of high quality treatment at affordable costs, regular follow up and accessible follow-up management as and when required. Cancer screening centres must have 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. The Committee, therefore, recommends the respective State Governments to smooth linkage between the screening facilities to diagnosis centers and subsequent treatment facilities like CHCs, District Hospitals and tertiary level hospitals.**

#### **Case Study: The National Institute of Cancer Prevention and Research, Noida.**

2.12 The Committee in its meeting held on 28<sup>th</sup> June, 2022 heard the views of Director, NICPR. NICPR is an ICMR Institute with the vision to catalyze prevention of common cancers – oral, breast and cervical – and non-communicable diseases, with emphasis on prevention through an integrated, multi-sectoral approach encompassing development of skilled health workforce for promoting wellness, screening, early diagnosis and treatment. The institute works on three verticals – research, capacity building and Information, Education and Communication (IEC) services for the public. The institute is engaged in various kinds of research in the field of clinical, epidemiological studies and various other modalities. The aim of cancer epidemiology is to understand where the Cancer is rising, falling etc. NICPR also participates in various systematic reviews and research studies and

also population-based studies. The organization also supports national programmes, i.e., Cancer Control Programme of the country, Population-based Cancer Registry and other programmes. The institute focuses on tobacco research and control. The operations of NICPR lay emphasis on preventive and promotive health.

2.12.1 The Director, NICPR during her submission to the Committee meeting held on June, 2022 apprised the Committee, that the Government of India in 2016 made an operational framework for management of common cancers and NICPR played a major role in framing these guidelines. According to the framework, the need is to build capacity of the healthcare providers for screening different types of cancers -- the oral, breast and cervical cancers. NICPR runs five programmes for capacity building, these programmes cater to the healthcare providers like gynaecologists, dental surgeons, medical officers, staff nurses and also the ASHA workers. Recently a programme for training for Cytopathologists was also initiated. Initially, these courses are online courses, followed by hands-on skill based workshop training.

2.12.3 The institute does liaisoning with the State Health Departments to impart training to medical health providers. The States send names of the officials who have to be trained, the institute then trains them. At the end of the training, there is a pre and post examination conducted. Successful candidates are provided with certificates to the effect that they have been trained. Following that, in the PHCs or CHCs, they can screen the patients. The institute also provides training for Colposcopy because many gynaecologists in the country are not trained for Colposcopy.

### **NICPR's Demonstration Projects**

#### **I. Screening and early detection of cervical, breast and oral cancer in Assam**

2.12.4 The aim of the project is capacity building of health staff in screening of cervical, breast & oral cancer and management of screened positive cases. Link the screening services to appropriate evaluation and treatment facilities. This project consisted of two phases viz. Phase 1: Training of Master Trainers and Phase 2: Implementation of screening in eligible population. The challenges observed during the project were lack of awareness in community, asymptomatic individuals not willing, screened positives reluctant to go to higher centres for further management, PHC Doctors not interested in screening, cancer screening - additional burden and ASHAs mainly involved in MCH activities.

2.12.5 Highlighting the outcomes of the project, the Director, NICPR mentioned that frontline health workers like ASHA are a potent workforce to promote and conduct home based screening and as the level of cancer awareness rises, the health seeking behaviour towards early detection may increase and consequently the cancer load in the country will hopefully begin to decline.

#### **II. Scaling up of implementation of primary HPV screening by self-sampling in Sikkim**

2.12.6 She apprised the Committee that this project also consisted of two phases viz. phase 1: capacity building of health care providers in cervical cancer screening and phase II: implementation of screening in eligible population using home-based sample collection by self-sampling

2.12.7 In this project the institute collected cervical samples after teaching the women how to collect self-samples. The institute conducted outreach programmes in neighbouring PHCs and involve students, ASHA workers and ANMs in that.

### **Population Based Cancer Registry**

2.13 The Director, NICPR further apprised the Committee that the institute has also set up a population-based cancer registry at the institute covering the rural and urban population of Gautam Buddha Nagar (G.B. Nagar) district of Uttar Pradesh.

**Aim:** To set up a Population-Based Cancer Registry at National Institute of Cancer Prevention & Research (ICMR-NICPR) covering the rural and urban population of Gautam Buddha Nagar (G.B. Nagar) district of Uttar Pradesh.

#### **Objectives:**

1. To find out age and sex-specific incidence & mortality data of G.B. Nagar district of Uttar Pradesh.
2. To find out cancer site-specific incidence & mortality data of G.B. Nagar district of Uttar Pradesh.

NICPR operates a WHO Framework Convention on Tobacco Control Knowledge Hub on Smokeless Tobacco. This is mandated with the task of generating awareness, expertise and knowledge and providing training, regionally and globally, on smokeless tobacco. The Director further apprised the Committee that eight per cent of pregnant women consume smokeless tobacco, the need is to integrate the information to the ante-natal care and help them so that maternal health and health of the baby improves. The institute conducts various webinars, seminars and online courses for healthcare providers so that they are trained in tobacco cessation.

**2.13.1 The Committee notes the mandate of NICPR with respect to Cancer prevention, awareness generation and research on prevention and diagnostic methodologies. The Committee notes that the institute is actively involved in studies to ascertain the prevalence of Cancer in different regions. The Committee recommends the Institute to widely publish the outcomes and findings of its studies in the public domain. The Committee takes note of the Institute's efforts in liaisoning with the State Health Departments to impart training to medical health providers. The Committee, in this regard, recommends the institute to improve its engagement with States so that more and more States send names of the officials who have to be trained, the institute must follow up with States which fail to send the names of the officials. The Institute must further ramp up its screening, awareness and prevention efforts by publishing more booklets and modules on prevention and screening in all the languages and distributing it through the ASHA and ANM workers. The institute should also ramp up its training activities in view of the increased future requirements for the cancer care in the country.**

## CHAPTER-III

### INSTITUTIONAL FRAMEWORK FOR CANCER CARE & MANAGEMENT

3.1 Institutional Framework for Cancer Care and Management refers to the diagnosis and treatment of cancer at various levels in the Govt. Health Care Delivery System which *inter-alia* includes Subcentre, Primary Health Centre (PHC), Community Health Centre (CHC), District Hospital besides medical colleges and tertiary care institutions. Financial and technical support is provided upto the District level. Even though health and hospitals are a State subject, the Central Government supplements the efforts of state govt in preventing and controlling cancer. To enhance the facilities at tertiary level, the Central Government is implementing strengthening of Tertiary Care for Cancer Centre (TCCC) scheme. Treatment of cancer is also through Central Government Hospitals/Institutions in different parts of the country such as All India Institute of Medical Sciences, Safdarjung Hospital, Dr. Ram Manohar Lohia Hospital, PGIMER Chandigarh, JIPMER Puducherry, Chittaranjan National Cancer Institute (CNCI), Kolkata etc.

3.1.1 The National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Disease & Stroke (NPCDCS) is being implemented since 2010 in India by the Ministry. National Cancer Control Programme operational since 1975 is now merged with NPCDCS since 2010. Under the aegis of Pradhan Manti Swasthya Suraksha Yojana (PMSSY), setting up of 22 new AIIMS and upgradation of 75 Govt. Medical Colleges has been taken up. Treatment of cancer under Ayushman Bharat - Pradhan Mantri Jan Arogya Yojana (AB-PMJAY) has been one of the prime focus areas to safeguard the beneficiaries from catastrophic expenditure of cancer treatment.

#### **Institutional Arrangement for Cancer-Patient Care**

3.2 Standard Treatment Guidelines for Oncology have been developed by expert groups in the Directorate General of Health Services, Ministry of Health & Family Welfare. These are for 11 types of cancers and available on the website of Clinical Establishment Act. There are guidelines for 20 different cancers brought out by Indian Council of Medical Research (ICMR).

#### **National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Disease & Stroke (NPCDCS)**

3.3.1 The Committee is given to understand that the National Cancer Control Program (NCCP) was started in 1975 with emphasis on prevention and early detection of oral, cervical and breast cancer, tobacco control and palliative care. In 2010, the National Programme for Prevention and Control of Cancer, Diabetes, Cardio-Vascular diseases and Stroke (NPCDCS) was launched and all the cancer control initiatives were taken up under the same umbrella of controlling all non-communicable diseases.

Broad Activities permissible under NCD flexi-pool for NPCDCS are as follows:

- 1) Health promotion including, IEC / BCC / SBCC;
- 2) Screening and case detection including Populationbased screening;

- 3) Management of NCDs
- 4) Integration with other programmes
- 5) Monitoring & Evaluation
- 6) Capacity Building and
- 7) Public Private Partnership

3.3.2 The Committee has been informed that screening of common NCDs including common cancers (viz. oral, breast and cervical) is also an integral part of service delivery under Ayushman Bharat- Health and Wellness Centres. Till date 80,010 HWCs have been operationalized out of the target of 1.5 lakh throughout India. The number of persons screened so far through Health and Wellness Centres includes 771.20 lakh for oral cancer, 386.10 lakhs for breast cancer and 262.49 lakh for cervical cancers. (Source: AB HWC portal)

3.3.3 ICMR's National Institute of Cancer Prevention & Research (NICPR) is the nodal agency for developing operational guidelines for screening of common cancers under NPCDCS. ICMR's NICPR also conducts online cancer screening training courses using ECHO (Extended Community Health Outcome) platform for Primary Health Centres (PHC) Medical Officers, Gynecologists, Dentists and Staff Nurses which is FREE of cost.

3.3.4 One third of cancers are tobacco related cancers & can be prevented. ICMR's NICPR has established a WHO FCTC Knowledge Hub on Smokeless Tobacco as the focal center for generation and dissemination of information on smokeless tobacco. Thematic areas of work of SLT Knowledge Hub include surveillance and monitoring, policy reform, products, health effects, economics and marketing and interventions (<http://untobaccocontrol.org/kh/smokeless-tobacco/>).

3.3.5 ICMR-NICPR and WHO FCTC SLT Hub provided inputs for the amendment of COTPA (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) (Amendment) Bill, 2020. Various training courses in cancer education and research are being imparted by national and international organizations viz: WHO, African and SAARC/ASEAN countries, INCTR and IAEA.

**3.3.6 The Committee observes that the merger of National Cancer Control Programme (NCCP) into the NPCDCS has reduced the focus and proper handling of cancer screening. The Committee notes that India lacks a robust policy on cancer control in India and there is an urgent need to strengthen the screening and early detection & diagnosis infrastructure in the country. The Committee, therefore, is of the opinion that cancer must be dealt with separately and must not be grouped under other lifestyle diseases. The Committee accordingly recommends the Ministry to devise a targeted plan for tackling cancer before it blows out of proportion and consume a major part of human and financial resources of the country.**

**3.3.7 The Committee is given to understand that there is a definite need for systematic data collection and aggregation, evaluating patterns of care, and health technology assessment to channelize scarce healthcare resources appropriately. The Committee, therefore, feels that systematic data collection and aggregation can optimally utilize the healthcare resources.**

**3.3.8 The Committee in its 134<sup>th</sup> Report on Demands for Grants 2022-21 of the Department of Health and Family Welfare had also noted that Rs. 175 crore was approved in BE 2021-22 for NPCDCS which was later reduced to Rs. 146.88 crore. The Committee believes that the allocation of funds should also be considerably increased for tackling cancer and other lifestyle diseases. The Committee reiterates that the Ministry must make a realistic requirement of funds to support the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke. The Committee would also recommend the Ministry to assess the continued relevance of the Scheme and the progress made towards achieving the envisaged objectives under the Scheme.**

**3.3.9 The Committee would also like to be apprised of SWOT analysis of the Scheme and recommends the Government to work upon the weakness and threats of the Scheme and take advantage of strength and opportunities of the Scheme for better result.**

### **Functioning of Non Communicable Disease (NCD) Cells**

3.4 Under the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS), NCD Clinics are being set up at District and CHC levels, to provide services for common NCDs (Diabetes, Hypertension and common Cancers viz. Oral, Breast and Cervical Cancers). In identified districts, Cardiac Care Units (CCU) and Day Care Centres are also being set up for providing facilities for emergency Cardiac Care and Cancer Chemotherapy respectively. Intervention on COPD, CKD and NAFLD are also included in the programme.

**Comparative position of persons attended the NCD Clinics and screened under NPCDCS for following years is as below:**

Year	Total Number Screened	Number of persons diagnosed with			
		Diabetes	Hypertension	CVDs	Common Cancer
2014-15	59,24,567	5,59,718 (9.45%)	7,15,382 (12.02%)	61,302 (1.03%)	11,385 (0.19%)
2015-16	1,29,00,368	10,67,774 (8.28%)	14,92,996 (11.57%)	89,922 (0.70%)	13,262 (0.10%)
2016-17	2,24,27,125	21,75,145 (9.70%)	27,12,204 (12.10%)	1,04,633 (0.47%)	39,081 (0.17%)
2017-18	4,65,75,176	37,28,436 (8.00%)	45,55,231 (9.78%)	1,83,548 (0.39%)	71,911 (0.15%)
2018-19	6,79,62,186	41,48,681 (6.1%)	50,67,912 (7.4%)	1,77,112 (0.26%)	1,45,430 (0.21%)
2019-20	6,60,95,757	49,96,389 (7.55%)	58,42,446 (8.83%)	2,26,411 (0.34%)	77,293 (0.12%)
2020-21	4,66,15,704	37,54,055 (8.05%)	44,17,013 (9.47%)	1,48,873 (0.32%)	58,602 (0.12%)

3.4.1 The Director, Dr B Borooah Cancer Institute in his submission before the Committee stated that the Government of India had launched an operational framework for the country's first National Cancer Screening program in 2016 under the NPCDCS scheme. Non Communicable Disease (NCD) Cells are being established at National, State and District levels for programme management, and NCD Clinics are being set up at District and CHC levels, to provide services for early diagnosis, treatment and follow-up for common NCDs including Cancer. However, due to lack of proper planning and implementation, the NCD Clinics are primarily functioning for diagnosis of hypertension and diabetes rather than screening and early detection of cancer. He further submitted that inspite of all the programmes in place, only 1.2% of the population is covered in cancer screening. It is therefore desirable that all the NCD clinics should be made fully functional under the complete supervision of Public Health Professionals. Emphasis should be laid on outreach camps for opportunistic screening, capacity building, survivorship, patient advocacy, health promotion, support for diagnosis and cost effective treatment.

**3.4.2 The Committee is disappointed to note that only 1.2% of the population is covered in population based cancer screening programme. The Committee notes that the Non Communicable Disease Cells could have been optimally utilized for screening of cancer patients, however, the NCDs have failed to emerge as centers of first line screening for cancer patients. The Committee strongly feels that early diagnosis of cancer is the best chance for successful treatment. With delay in detection of cancer, the cost of treatment and care also increases as associated risks become graver. The Committee recommends the Ministry to ensure that the NCD Clinics are made fully functional and robust screening of common cancer is done in the clinics. The Committee also recommends the Ministry to provide adequate training to the health care professionals at the NCD Clinics/ Primary Health Centre/ Community Health Centre for the screening of common Cancer.**

**3.4.3 The Committee observes that the prevalence of NCDs have been on a rise, however, the Scheme has failed to achieve the desired outcomes. The Committee is also of the opinion that there is a need to generate awareness among the general public regarding the regular screening of cancer in the NCD clinics or some other private centers. The Committee recommends the Ministry to conduct more awareness camps and work on capacity building, patient advocacy, health promotion, etc. The Committee further recommends the Ministry to put in place a mechanism wherein probable cancer positive individuals are compulsorily referred to the cancer centers where they undergo further elaborate tests. The treatment must commence at the earliest so that the survival rates are increased. The success of the National Cancer Control Plan will only be ensured when early cancer detection is followed by early treatment. The Committee observes that developing an effective preventive strategy for tackling NCDs need a multi-sectoral approach.**

### **Tertiary Care for Cancer**

3.5 The Ministry of Health and Family Welfare submitted that to enhance the facilities for tertiary care of cancer, the Central Government is implementing 'Strengthening of Tertiary Care Cancer Facilities' Scheme. Under the scheme, support is provided to States/UTs for setting up of State Cancer Institutes (SCIs) and Tertiary Cancer Care Centres (TCCCs) in different parts of the country. The financial assistance is for procurement of radio therapy equipment, diagnostic equipment, surgical equipment, enhancement of indoor civil work and

patient facility for cancer and such other purposes relevant for diagnosis, treatment and care of cancer. The maximum permissible assistance for SCI is Rs. 120 crores and for TCCC is Rs. 45 crores. This is inclusive of State share of 40% (for North East and Hill States 10%). Upto a maximum of 30% of the sanctioned amount will be permitted to be used for civil/electrical work (including renovation), and improvement of infrastructure. A total of 39 institutions (19 SCI and 20 TCCC) have been approved. 27 Regional Cancer Centres were financially assisted till 2004 under the earlier National Cancer Control Programme. These erstwhile RCCs continued the work in cancer care. Till date, seven institutes have been completed.

3.5.1 Further, Oncology is also one of the focus areas in case of new AIIMS and many upgraded institutions under Pradhan Mantri Swasthya Suraksha Yojana (PMSSY). Setting up of National Cancer Institute at Jhajjar in Haryana and strengthening of Chittaranjan National Cancer Institute, Kolkata, are also steps in the direction of improving tertiary cancer care facilities.

**Table 4: Details of SCI and TCCC**

S No	State	Name of the Institute	SCI / TCCC
1	Andhra Pradesh	Kurnool Medical College, Kurnool	SCI
2	Assam	Gauhati Medical College & Hospital, Guwahati	SCI
3	Bihar	Indira Gandhi Institute of Medical Sciences, Patna	SCI
4	Chhattisgarh	Chhattisgarh Institute of Medical Sciences, Bilaspur	SCI
5	Delhi	Lok Nayak Hospital	TCCC
6	Gujarat	Gujarat Cancer Research Institute, Ahmedabad	SCI
7	Goa	Goa Medical College, Panaji	TCCC
8	Haryana	Civil Hospital, Ambala Cantt	TCCC
9	Himachal Pradesh	Indira Gandhi Medical College, Shimla	TCCC
10	Himachal Pradesh	Shri Lal Bahadur Shastri Medical College, Mandi	TCCC
11	Jammu & Kashmir	Sher-i-Kashmir Institute of Medical Sciences, Srinagar	SCI
12		Government Medical College, Jammu	SCI
13	Jharkhand	Rajendra Institute of Medical Sciences, Ranchi	SCI
14	Karnataka	Kidwai Memorial Institute of Oncology (RCC), Bangaluru	SCI
15		Mandya Institute of Medical Sciences, Mandya	TCCC
16	Kerala	Regional Cancer Centre, Tjiruvananthapuram	SCI
17		Government Medical College, Kozhikode	TCCC
18	Madhya Pradesh	G.R. Medical College, Gwalior	TCCC
19		Netaji Subhas Chandra Bose Medical College, Jabalpur	SCI
20	Maharashtra	Rashtrasant Tukdoji Regional Cancer Hospital & Research Centre, Nagpur	TCCC
21		Government Medical College, Aurangabad	SCI
22		Vivekanand Foundation & Research Centre, Latur	TCCC

23	Mizoram	Mizoram State Cancer Institute, Aizawl	TCCC
24	Nagaland	District Hospital, Kohima	TCCC
25	Odisha	Acharya Harihar Regional Cancer Centre, Cuttack	SCI
26	Punjab	Government Medical College, Amritsar	SCI
27		Civil Hospital, Fazilka	TCCC
28	Rajasthan	S P Medical College, Bikaner	TCCC
29		SMS Medical College, Jaipur	SCI
30		Jhalawar Medical College & Hospital, Jhalawar	TCCC
31	Sikkim	Multispecialty Hospital at Sochyang (Sichey), near Gangtok, Sikkim	TCCC
32	Tamil Nadu	Cancer Institute (RCC), Adyar, Chennai	SCI
33	Telangana	MNJ Institute of Oncology & RCC, Hyderabad	SCI
34	Tripura	Cancer Hospital (RCC), Agartala	SCI
35	Uttar Pradesh	Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow	TCCC
36	Uttarakhand	Government Medical College, Haldwani	SCI
37	West Bengal	Government Medical College, Burdwan	TCCC
38		Murshidabad Medical College & Hospital, Berhampore, Murshidabad	TCCC
39		Sagore Dutta Memorial Medical College and Hospital, Kolkata	TCCC

3.5.2 Attention of the Committee is further drawn to the submission of the Ministry of Health and Family Welfare in its Action Taken Note on the recommendations/observations contained in the 126th Report. The Ministry had submitted that the responsibility of completion of projects lies with the States/UTs concerned. The Ministry of Health and Family Welfare regularly seeks the physical and financial progress reports from the concerned centre and also directs them to complete the project on time.

3.5.3 During the examination of the Demands for Grants 2022-23 of the Department of Health and Family Welfare, the Ministry had submitted that through regular follow up and meetings it is committed to complete all 19 SCIs and 20 TCCCs by 31.3.2024. In this regard a meeting was held under the chairmanship of Secretary, Ministry of Health & Family Welfare, Govt of India on 23 Nov, 2021 on Review-cum-Orientation Workshop for Tertiary Care Programmes under NPCDCS.

**3.5.4 The Committee notes that the Cabinet Committee on Economic Affairs (CCEA) had approved the Scheme of "Strengthening of Tertiary Care Cancer Facilities" in 2013 which was aimed to enhance the tertiary care facilities in the country. The Committee however, notes that the completion of all the 19 SCIs and 20 TCCCs has been considerably delayed and is expected to be completed by 31.03.2024. The Committee further notes that the States are the main implementing agencies under the Scheme and both the States and the Centre contribute to the Scheme. The Committee is of the view that the States and the Centre shall work in tandem to complete all the SCIs and TCCCs within the revised schedule. The Committee accordingly recommends the Ministry to hold regular review meetings with the States and ensure the successful completion of all the 19 State Cancer institute (SCI) and 20 Tertiary Cancer Care Centre (TCCC).**

## Pradhan Mantri Swasthya Suraksha Yojana (PMSSY)

3.6 Pradhan Mantri Swasthya Suraksha Yojana (PMSSY), a Central Sector Scheme, was announced by the Honorable Prime Minister in the year 2003 with the objectives of correcting regional imbalances in the availability of affordable/reliable tertiary healthcare services and augment facilities for quality medical education in the country. The Cabinet Committee on Economic Affairs (CCEA), in March 2006, approved the scheme of PMSSY proposed by the Ministry of Health and Family Welfare for, setting up of six AIIMS like Institutions in the States of Bihar (Patna), Madhya Pradesh (Bhopal), Odisha (Bhubaneswar), Rajasthan (Jodhpur), Chhattisgarh (Raipur) and Uttarakhand (Rishikesh) at a cost of Rs. 332.00 crore per AIIMS like institution. Subsequently, due to substantial changes in the cost and the scope of work, the Ministry in February 2010 submitted revised cost estimates of Rs. 820.00 crore per AIIMS like institution to CCEA which was approved by the latter on 19th March 2010. PMSSY has two components, viz (i) Setting up of AIIMS like Institutions and (ii) Upgradation of Government Medical Colleges/Institutions (GMCs).

3.6.1 Presently, setting up of 22 new AIIMS and upgradation of 75 Govt. Medical Colleges has been approved under the aegis of PMSSY. The Ministry further submitted that Cancer treatment facility has been envisaged in all the 22 AIIMS. Out of these, six AIIMS at Bhopal, Bhubaneswar, Jodhpur, Patna, Raipur and Rishikesh are already functional where cancer treatment facility is operational. These AIIMS have been provided with state-of-art diagnostic, medical and surgical care facilities. Cancer treatment facilities have also been created / planned in 13 State Govt. Medical Colleges which have been taken up for upgradation under PMSSY. The list of the projects is given below.

### Status of 22 New AIIMS

Sl.	AIIMS	Status	Sl.	AIIMS	Status
1	Bhopal	Functional with Cancer Treatment Facility	12	Bathinda	Being set up with Cancer Treatment Facility
2	Bhubaneswar		13	Guwahati	
3	Jodhpur		14	Bilaspur	
4	Patna		15	Deoghar	
5	Raipur		16	Jammu	
6	Rishikesh		17	Kashmir	
7	Raebareli	Being set up with Cancer Treatment Facility	18	Madurai	
8	Mangalagiri		19	Rajkot	
9	Nagpur		20	Bibinagar	
10	Kalyani		21	Manethi	
11	Gorakhpur		22	Darbhangha	

### 3.6.2 List of State Govt. Medical Colleges being upgraded for cancer treatment

Sl.	State	Name of Govt Medical College	Facility
<b>Phase-I</b>			
1.	Jharkhand	RIMS Ranchi	68 bedded Oncology Block
<b>Phase-II</b>			
2.	Punjab	Govt Medical College Amritsar	Oncology
3.	Himachal Pradesh	Rajendra Prasad Govt. Medical College, Tanda	Oncology

<b>Phase-III</b>			
4	Karnataka	Karnataka Institute of Medical Sciences, Hubli	Medical Oncology
5	Rajasthan	SP Medical College, Bikaner	Surgical Oncology
6	Rajasthan	RNT Medical College, Udaipur	Radiotherapy/Oncology
7	Telangana	Kakatiya Medical College, Warangal	Medical Oncology
8	Uttar Pradesh	Govt Medical College, Gorakhpur	Surgical Oncology
10	Uttar Pradesh	M.L.N Government Medical College, Allahabad	Surgical Oncology
11.	Uttar Pradesh	LLRM Medical College, Meerut.	Radiotherapy
<b>Phase-IV</b>			
12	Uttar Pradesh	Govt Medical College, Agra	Radiation /Medical Oncology
13.	Bihar	Patna	Radiotherapy (equipment)

**3.6.3 The Committee observes that among the 22 new AIIMS, presently cancer treatment facility is available only in 6 AIIMS i.e. Bhopal, Bhubaneswar, Jodhpur, Patna, Raipur and Rishikesh. The Committee further finds that Cancer treatment facilities have also been created/ planned in 13 State Government Medical Colleges which have been taken up for up-gradation under PMSSY. The Committee notes that the main objective of PMSSY was to correct regional imbalances in the availability of affordable/reliable tertiary healthcare services. With an increase in cancer incidences across the country, it is all the more necessary to strengthen the tertiary healthcare services especially the cancer treatment facilities in the hospitals/Institutes. The Committee accordingly recommends the Ministry to take measures to expedite the setting up of cancer treatment facilities in AIIMS like Institutions and Government Medical Colleges under PMSSY. The Committee strongly recommends the Ministry to ensure that the required manpower is available in these Institutes and all the Departments of Oncology are made functional within a stipulated time frame.**

**3.6.4 The Committee believes that timely diagnosis of cancer is crucial for providing comprehensive cancer care, however, the Government Medical Colleges and Hospitals at district level lack the infrastructure and facilities for accurate cancer diagnosis. The Committee strongly recommends that under the GMC upgradation component of the PMSSY, the Ministry must ensure that screening and diagnostic tests especially for common cancer are present in the District Hospitals. The Ministry of Health and Family Welfare must also ensure that adequate number of healthcare workforce is present in the GMCs that are well trained in cancer screening and diagnosis.**

### **National Cancer Grid**

**3.7 The National Cancer Grid, an initiative of the Department of Atomic Energy, Government of India, was created in 2012 with the broad vision of creating uniform standards of cancer care across India. Nine years later, it has grown to a large network of 255**

cancer centres, research institutes, patient advocacy groups, charitable organizations and professional societies. Between the member organizations of the NCG, the network treats over 750,000 new patients with cancer annually, which is over 60% of all of India's cancer burden.

3.7.1 The National Cancer Grid guidelines on management of common cancers has been endorsed by all participating centres, which act as uniform standards of patient care and is periodically modified whenever new evidence is generated. Adherence to these consensus guidelines is also being evaluated by conducting institutional peer reviews of the constituent centres. The second edition of the NCG guidelines is resource stratified and divides the guidelines into optional (which reflect the state of the art, without cost considerations), optimal (which takes value into account while making treatment recommendations) and essential (which takes value as well as availability of expertise and infrastructure). These guidelines have been adopted by the AB-PMJAY to rationalize treatment packages & tariffs and is linked to reimbursement under the scheme.

3.7.2 Small and medium sized cancer centres find it difficult to negotiate competitive prices with equipment manufacturers and the pharmaceutical industry. By aggregating the demands from many centres, the NCG worked on a solution wherein "price discovery" of commonly used, high-value items are negotiated with industry, thereby passing on the benefits to member centres and onwards to patients. Using transparent policies for tendering and a web-enabled e-tendering platform, this initiative has brought down current costs of cancer care significantly (average of 55% discount on MRP) while maintaining the quality of drugs.

3.7.3 The National Cancer Grid (NCG) works on the following areas for uniform standards of cancer care and towards affordability and access:

- i. Uniform standards of care – NCG Consensus Guidelines
- ii. External Quality Assurance Schemes (EQAS)
- iii. Second opinion service for patients – "Navya"
- iv. NCG Virtual Tumor Boards
- v. Price Discovery Cell / Group negotiation for equipment, drugs and consumables
- vi. Continuing Medical Education – NCG National Cancer Library and Discovery tool "Akshara"
- vii. Unique Educational Initiatives – "Traveling Schools of Pathology and Oncology Nursing"
- viii. Training in Cancer Research Methods – International Collaboration on Research methods Development in Oncology – CreDO workshop
- ix. NCG funded multicentric collaborative research

3.7.4 The NCG has also developed cancer treatment guidelines for various cancers (31 different types of cancers) for member institutions, however, the prerogative of using any modality/protocol/drug in cancer patients is of the physician, the institution concerned, and the available guidelines are only indicative/suggestive and not mandatory.

3.7.5 The Departments of Health Research (DHR), ICMR has developed DHR-ICMR Advanced Molecular Oncology Diagnostic Services (DIAMoNDS) on a Hub and Spoke model. The objective is to provide free of cost pathological diagnosis of cancer to patients. In first phase, Breast and Lung cancer have been included at 4 major centres (AIIMS-New Delhi, TMH-Mumbai, CMC-Vellore, TMC-Kolkata) as hubs and another 7 centres in different parts of India as spokes. Till February 2022, a total of 2700 patients have benefited.

Next 2 cancers such as colon and uterus have been added for free testing in the list in March 2022.

3.7.6 As per the World Cancer Report, 2020 India had an estimated 1.16 million new cancer cases in 2018. The Report further stated that one in 10 Indians will develop cancer during their lifetime and one in 15 will die of the disease. In India, the six most common cancer types were breast cancer, oral cancer, cervical cancer, lung cancer, stomach cancer, and colorectal cancer. All of these cancers together account for 49% of all-new cancer cases.

**3.7.7 The Committee commends the Department of Atomic Energy for creating the National Cancer Grid and believes that the DAE along with the Ministry of Health and Family Welfare must make consistent efforts to bring in a uniform criterion for prevention, early diagnosis, treatment protocol and follow up of cancer patients. The Committee would also like the Ministry of Health and Family Welfare to explore a process of audit and peer review of the Cancer Centres and monitor the progress of Cancer Centres under the National Cancer Grid in tandem with the Department of Atomic Energy.**

**3.7.8 The Committee notes that there is wide disparity in the incidence and mortality of cancer across the different regions of the country. The Committee notes that there is huge variation in the treatment procedure followed and the standards of cancer diagnosis across the country. The Committee believes that uniform high standards of cancer care must be provided throughout the country. The Government machinery must ensure that the Cancer Centres across the country follow a common standard management guideline for cancer care. The Committee further recommends the Ministry of Health and Family Welfare to bring in a mechanism to capture the data of each cancer patient and assess the pattern of cancer across the country.**

**3.7.9 The Committee accordingly recommends the Ministry to periodically modify the Guidelines as per new researches and studies on cancer. The Committee further recommends that the Government should make efforts to strengthen the network of Cancer Centres and include more Cancer Centres under the National Cancer Grid. The Committee hopes that the Cancer Centres across the country are able to benefit from the State of the art Cancer Centres under the NCG. The Committee would also like the Government to explore the idea of establishing a mentor institute in each region which facilitates training, cancer research and more collaboration among the institutes of the region.**

### **Hub and Spoke Model of Cancer Care**

3.8 The Hub and Spoke model stands for a network of hospitals on two levels. SCI/TCCCs are envisaged for cancer treatment as Hub and Spoke for providing cancer care, giving support to district hospitals and medical colleges. SCI will serve as the nodal and apex Institution to mentor other Government Institutes (including TCCC and RCC). Similarly, the TCCC should mentor cancer related activities including at the district level and below in their respective footprint area (the areas from where patients are accessing the TCCC). SCI would be hub and TCCCs as spokes, and facilities being created under NHM – District NCD clinics, CHC NCD clinics, Day Care Centres – as sub-spokes. Creating a network of these facilities is required for continuum of care, for which steps are being taken.

3.8.1 The Department of Atomic Energy, in its submission to the Committee, has stated that a distributed model of cancer care is required to offer patients high quality cancer care at their doorsteps. Common and less complex cancer care should be provided close to patients' homes (spokes) to create minimum disruption in their lives and that of their families. Treatment of uncommon cancers and those with complex treatment protocols require management in expert centres of excellence (hubs). However, to avoid over-burdening the hubs, the spokes need to be reasonably capable of handling less complex and common cancer types in the region. This strategy would be extremely helpful to minimize costs as well as inconvenience to patients and their families. Delivery of care would be at the spokes to the extent possible, with treatment planning even for uncommon cancers being done in the hubs and actual treatment delivered at the spokes.

3.8.2 The Department of Atomic Energy further submitted that one hub should cover an approximate population of about 4 crores – here; the estimated cancer burden would be about 30 to 40,000 new patients annually. Similarly, a spoke should cover a population of 1 crore, (estimated cancer burden 8000 to 10,000 new patients annually) depending on geographic and access issues. Therefore, about 30 hubs and 130 spokes would need to be created to bridge the gaps in access. The DAE has already created six hubs and one spoke in various parts of the country; moreover, there are existing cancer centres which may be upgraded to hubs or spokes depending on their existing infrastructure and capabilities. In locations where there are no existing cancer centres, new facilities need to be created over the next 10 years. This document summarizes the plan to create this infrastructure for the country.

3.8.3 The DAE further proposed a detailed mapping exercise to identify region-wise cancer burden, common types of cancer and the existing facilities to manage them. This would be helpful in prioritizing the phasing of the proposed hubs and spokes. The next step would be to identify centres which can be upgraded to serve as hubs and spokes; it is likely that some regions would require the setting up of new cancer centres in a phased manner. TMC would work closely with the respective states to identify land, which we expect to be provided free of cost by the concerned state. The requirements are approximately 50 acres for a hub and 10 acres for a spoke. It is essential that the proposed land is –

1. In close proximity to an airport, railway station, and has good road access
2. Is adjacent or close to a medical college hospital or district general hospital

3.8.4 Hubs will be comprehensive cancer facilities with state of the art equipment and infrastructure, along with trained expert human resources to treat all cancers. Each hub is envisioned as a 300 bedded facility, built at an estimated cost of Rs.650 crores. The annual recurring expenditure for the facility (working on the TMC model) would be Rs.110 to 120 crores. Spokes would be 100 bedded facilities, capable of managing most common cancers and uncommon cancers with oversight from the hub. Highly complex treatments like bone marrow transplant, complex surgical interventions and high-end radiation will not be available at the spokes. The cost of setting up such a spoke would be approximately Rs.380 crores, with a recurring annual expenditure of Rs.35 to 40 crores. Each of these hubs and spokes will have a "Guest House" to provide accommodation for patients and their families – this is expected to cost Rs.80 crores where hubs are located and Rs.30 crores where spokes are located, with an annual running expenditure of Rs.20 crores and Rs.8 crores respectively. Approximately, Rs.13,000 crores and Rs.22,000 crores will be required for hub and spoke respectively.

**3.8.5** The Committee notes that cancer cases in India are diagnosed at a later stage which is a major cause of high mortality to incidence ratio and increase in cancer care expenditure. The Committee believes that a strong network of cancer care centres across the country would facilitate early diagnosis of cancer cases and greatly reduce the burden of cancer cases in India. The Hub and Spoke Model is an efficient distribution model of providing comprehensive cancer care by creation of hubs and spokes in all the States of the country. The Committee notes that TMC has worked in close contact with the State Governments to create hubs and spokes in States. The Committee believes that such collaborations will enable in further strengthening the cancer care infrastructure along with knowledge, skill and resource sharing. The Committee appreciates the work done by TMC and DAE and advocates the need for establishing government funded hub and spoke model of cancer care across States. The Committee further believes that ensuring adequate human resource in Cancer centers under the hub and spoke model is also crucial for complete operationalization of the Centers.

**3.8.6** The Committee agrees with the Department of Atomic Energy that there is a need to identify region wise cancer burden and common types of cancer in different regions. The Committee is of the opinion that a correct assessment of the cancer burden would facilitate formulation of an effective strategy for creation of hubs and spokes in the country. The Committee recommends the Ministry of Health and Family Welfare to work in close collaboration with the Department of Atomic Energy to decide a timeline for implementing the hub and spoke model in each State. The Committee urges upon the Government to ensure that the existing SCI/TCCCs are upgraded to hubs and spokes depending on their existing infrastructure and capabilities.

**3.8.7** The Committee is of the considered view that the Union Government should take a lead in setting up of new cancer centres in a phased manner and ensure that the State Governments must provide land and other necessary approvals without any delay to the projects. With such an apex Institute like TMC on board, the Committee expects the State Governments to benefit from its experiences and technical expertise of TMC. The State Governments must take a proactive approach in identifying the land and sending the necessary proposals to TMC without any delay and hassels.

**3.8.8** The Committee also notes that the most common form of treatment is radiotherapy and patients continue to attend hospitals for many days. The Government must ensure that guest houses are established near the Cancer Centers where the patients can stay at subsidized costs. Making adequate arrangements for patients stay will further reduce the cost of cancer treatment. The Committee, accordingly, recommends the Ministry to make facilities for subsidized or free accommodation in each of the hubs and spokes. This will ensure that the out-station patients can complete the treatment without being forced to spend on accommodation in hotels or hostels in the city.

### **Pradhan Mantri Jan Arogya Yojana (PM-JAY)**

3.9 'Ayushman Bharat' programme is aimed towards provision of promotive, preventive, curative, palliative and rehabilitative aspects of Universal Health Coverage. Adopting continuum of care approach, Ayushman Bharat is being implemented through two

interrelated components, viz., Health and Wellness Centers (HWCs) to provide primary care and Pradhan Mantri Jan Arogya Yojana for providing financial protection for accessing hospitalization care at the secondary and tertiary levels. Hence, Ayushman Bharat involves-

1. Setting up 1.5 lakh Health and Wellness Centres (HWCs) to provide comprehensive primary health care including for non-communicable diseases and maternal and child health services.
2. Providing health cover of Rs. 5 lakh per family per year for secondary and tertiary care hospitalization to around 10.74 crore poor and vulnerable families (approx. 50 crore individuals) under Ayushman Bharat – Pradhan Mantri Jan Arogya Yojana (AB-PMJAY).

3.9.1 AB-PMJAY was launched on 23.09.2018 as an entitlement- based scheme, which covers deprived families in rural areas and families of workers of identified occupational categories in urban areas, as per the Socio-Economic Caste Census (SECC) database. Further, all such beneficiary families under erstwhile Rashtriya Swasthya Bima Yojana that do not figure in the targeted groups as per SECC data are also covered under PMJAY.

3.9.2 Under AB-PMJAY, the entitled beneficiary families get an annual defined health cover of Rs. 5 lakh per family on a family floater basis. This cover is able to take care of almost all secondary care and most of tertiary care procedures. There is no restriction on family size, ensuring all members of designated families specifically girl child and senior citizens get coverage.

3.9.3 AB-PMJAY is a centrally sponsored scheme. It is entirely funded by Government and the funding is shared between Centre and State Governments. The ratio of contribution towards premium between Centre and States is 60:40 in all States except North Eastern States & the Himalayan States where the ratio is 90:10 with an upper limit for Centre. In the case of Union Territories, the Central contribution of premium is 100% for UTs without legislature, while it is in the ratio of 60:40 for those with legislature.

3.9.4 Cashless and paperless access to services is provided to the beneficiary at the point of service in any (both public and private) empanelled hospital across India. In other words, a beneficiary from one State can avail benefits from an empanelled Hospital anywhere in the Country. The State Governments have been given the flexibility to decide on the mode of implementation of the scheme. They can implement the scheme either through insurance companies, or directly through trust/ society, or in a mixed mode i.e. partly insurance mode and partly trust mode.

3.9.5 A well-defined Complaint and Public Grievance Redressal Mechanism, has been put in place through which complaints/ grievances are registered, acknowledged, escalated for relevant action, resolved and monitored. A robust IT system has been created for implementation of the scheme. At National level, National Health Authority (NHA) has been set up as an attached office to Ministry of Health and Family Welfare to manage the implementation of the scheme.

3.9.6 The Ministry of Health and Family Welfare further submitted that the treatment of cancer under Ayushman Bharat - Pradhan Mantri Jan Arogya Yojana (AB-PMJAY) has been one of the prime focus areas to safeguard the beneficiaries from catastrophic expenditure of cancer treatment. Health insurance cover of Rs. 5 lakhs per family per year for secondary or tertiary care hospitalization to over Rs.10.74 crore beneficiary families identified from SECC 2011 database is provided. AB-PMJAY provides treatment corresponding to a total of 1,669 procedures under 26 different specialties for NCDs including Cancer. The treatment packages

under AB-PMJAY are very comprehensive covering various treatment related aspects such as drugs and diagnostic services. Chemotherapy and Radiotherapy packages, along with surgical oncology are covered as part of cancer treatment under the scheme. A total of 435 procedures have been defined for the treatment of cancer.

3.9.7 The Department of Atomic Energy in its written submission stated that NHA has partnered with the NCG in ensuring that the reimbursement scheme incorporates quality by authorizing treatment protocols which are adherent to the NCG resource stratified management guidelines. The NCG is also working with the NHA to rationalize treatment packages and tariffs under the AB-PMJAY, and empanelling more of the NCG member organizations for treatment under the scheme. This collaboration is likely to be a game changer in introducing quality parameters and metrics in what has been a largely unregulated healthcare delivery system.

3.9.8 Pfizer in its written submission stated that many oral therapies already listed as essential (or mandatory) or preferred (cost effective with evidence of efficacy) by National Cancer Grid in their guidelines published in 2019-20 are currently not covered under AB PMJAY for its beneficiaries, whilst they may already be listed in other Government sponsored schemes like CGHS, Army, ESI, Railways etc. Even for the Government sponsored scheme where the therapies are included, a patient undergoes navigational and reimbursement/approval challenges for getting care.

3.9.9 Pfizer further stated that linkages with other Central Government and State Government schemes like National Programme for prevention and control of Cancer, Diabetes, Cardiovascular diseases and Stroke (NPCDCS) / Rashtriya Arogya Nidhi (Rs. 15 lakhs) / Health Minister's Discretionary Grant (Rs. 1.25 lakh) and State schemes may be explored where the cost of these therapies may require further support beyond Rs. 5 lakhs per year per family under AB PMJAY. Oncology top-up cover similar to corpus maintained in some of the States (like Tamil Nadu) for funding treatment beyond basic cover may be set up. This oncology specific corpus may be set up independent to linkage with other schemes – for example, a separate fund for rare diseases for Rs. 50 lakh is being proposed to be set up in addition to Rashtriya Arogya Nidhi.

3.9.10 Pfizer further submitted that under Ayushman Bharat innovative funding models must be considered for inclusion of oncology treatments like

- i. Considering models like Patient Support/Assistance Programs within AB-PMJAY instead of a flat discounted price model to make it more sustainable for industry and government to collaborate for ensuring access to these therapies (like UK and other countries)
- ii. For countries with low GDP per capita, particularly in Low- and Middle-Income Countries (LMICs), many products in the prioritized areas of high-end drugs, implants and advanced diagnostics for oncology (with a small number of patients) may fall below a defined financial threshold while evaluating for inclusion. Thus, similar to other countries, a differentiated (or higher) financial threshold for Oncology may be considered for inclusion.
- iii. Differential pricing may be negotiated for bottom 40% population of the country covered under AB PMJAY with referencing protection for other payers and consumers.

**3.9.11** The Committee finds that AB-PMJAY is the flagship scheme of the Government that aims to provide comprehensive healthcare services to the beneficiaries, nevertheless, lack of awareness and poor screening services have been major challenges in providing cancer care under the Scheme. The Committee observes that PMJAY provides support for medical treatment for underprivileged families, however, the Committee believes that the Scheme should be extended to include diagnostic tests and other services. The Committee notes that initial investigations can be very expensive and is often the reason that leads to delay in treatment. The Committee accordingly, recommends the Ministry to include various types of necessary diagnostic tests under the Scheme so that timely detection of cancer can improve the cancer mortality rate.

**3.9.12** The Committee takes into account that the Scheme was aimed at reducing catastrophic expenditure for hospitalizations so that entitled families do not face any financial hardship. The Committee observes that doctors' entire prescription as well as all forms of latest therapy is not covered under Ayushman Bharat which leads to compromise in quality of treatment. The Committee, accordingly, recommends the Ministry to update the list of medication regularly in line with advancement in technology and treatment procedures. The Committee agrees with the view of Pfizer and recommends the Ministry of Health and Family Welfare to explore innovative funding models for inclusion of more targeted oncology treatments under AB-PMJAY.

**3.9.13** The Committee notes that Oncology has been one of the most used tertiary specialities in PMJAY which reaffirms the urgent need to review cancer treatment packages and expand the cancer services under the Scheme. The Committee, therefore, appreciates the partnering of NHA with NCG which will incorporate quality parameters along with empanelling of more NCG member organization under PMJAY. The Committee, in this regard, recommends the Ministry to include oral therapies that have already been listed as essential (or mandatory) or preferred (cost effective with evidence of efficacy) by National Cancer Grid under AB-PMJAY. The Committee advises the Ministry of Health and Family Welfare to review the existing cancer treatment packages and standard treatments covered under the Scheme.

**3.9.14** The Committee believes that integration of NHA with NCG will facilitate linking of cancer registry with repository of data under the PMJAY Scheme. Such measure will not only improve the accuracy of the cancer registry but also ensure a smooth referral and follow up system. The Committee believes that early screening and diagnosis of cancer is crucial for effective treatment of the cancer.

**3.9.15** The Committee notes that SECC data is the criteria for the beneficiaries under the PMJAY and some States have expanded the list of entitled beneficiaries under similar schemes. The Committee desired that SECC data not only need to be updated to broad base the scheme but PMJAY and other similar schemes as operational in various states should also aim at to provide financial assurance to patients suffering from cancer and other diseases.

**3.9.16** The Committee believes that a mandatory screening of beneficiaries of Government Health Scheme for common cancers will help increase the scope of the screening program. The Committee, in this connection, recommends the Ministry to conduct a mandatory annual cancer screening checkup for all Ayushman Bharat beneficiaries which will facilitate early cancer diagnosis. The Committee reiterates that

**such exchange of patient care information will not only help in better cancer management but also a more accurate cancer database.**

### **Important Institutions for Cancer-Patient Care**

#### **Chittaranjan National Cancer Institute, Kolkata**

3.10 Chittaranjan National Cancer Institute, Kolkata is one of the premier centres under Ministry of Health & Family Welfare for Cancer. It submitted that RuplalNandy Memorial Cancer Research Centre (RNMCR), being the field extension Center of CNCI, has been developed as a palliative care centre, Community based cancer awareness, screening and early detection and home based palliative care services conducted for the population of the district of Hooghly and surrounding districts. The Palliative Care Unit has been set up in collaboration with RumaAbedona Hospice Care. This center can be developed as the nodal center for cancer control activities including palliative care as per the District Cancer Control Program guidelines under the National Cancer Control Program (NCCP).

3.10.1 Rigorous home visits are to be done for which adequate number of human resources comprising of trained physicians, nurses, volunteers, physiotherapists can be recruited by CNCI after creation of posts specific for the Department. Since the terminally ill patients are almost at the end of their penny, supply of free medications both to decrease pain and for supporting therapy can be provided to the poor deserving patients.

3.10.2 CNCI felt that it can develop itself into a referral centre for PALLIATIVE CARE to all Institutes associated with cancer treatment in Eastern India. The Institute has collaborated with Pallium India for recruitment of manpower and introduction of various other Fellowships in this field. Director, CNCI in his submission before the Committee further stated that there is a need to incorporate telemedicine services from the PHCs to district and sub-divisional hospitals to the referral hospitals. This will further ensure a proper referral mechanism in cancer care packages as well as Government insurance Schemes like Ayushman Bharat and Swasthya Sathi in West Bengal.

#### 3.10.3 SWOT Analysis of CNCI:

<b>Strength</b>	<b>Weakness</b>
(i) Provision of high quality health care at subsidized and affordable rate (ii) Availability of sophisticated medical equipment such as Dual Energy Linear Accelerator with IMRT, VMAT, IGRT and SRT facilities, CT Simulator, Integrated Brachytherapy Unit , Video Laryngoscope. (iii) Availability of modern Operation Theatre with Endoscopy and Laparoscopic-surgery facilities. (iv) In house pharmacy Affordable Medicines and Reliable Implants for Treatment (AMRIT), Histopathology,	(i) Around 300 posts are in the process of being created for second campus and will be filled up. (ii) The existing staff at old campus find it difficult to shift to new campus since it is far away from the central location. (iii) This is not considered as a teaching institution hence not recognised by Medical Council of India. However, various DNB courses are running.

<p>clinical biochemistry and blood bank facility.</p> <p>(v) Focus on Basic and Translational research on cancer</p> <p>(vi) PhD programs are conducted under Jadavpur University, Calcutta University and West Bengal University of Health Sciences. Post Graduate Medical courses (DNB) in Surgical Oncology, Radiotherapy and Pathology and Post MSc Diploma in Medical Physics are conducted.</p>	
<p><b>Opportunities</b></p>	<p><b>Threats</b></p>
<p>(i) There is a huge requirement of tertiary level cancer care facilities in India with increasing cancer disease burden. Starting of the 460 bedded hospital at New Campus will add to tertiary cancer care facilities.</p> <p>(ii) Adequate space &amp; infrastructure are available at second campus of CNCI and majority of cancer services can be provided from this campus. This will result in optimal utilization of space and facility at New Campus and will reduce waiting list at the existing campus for cancer patients.</p>	<p>(i) The building of old campus is very old and has no scope of expansion there.</p>

**3.10.4 The Committee notes that CNCI has been providing healthcare services to the masses, however, there is delay in the recruitment of healthcare professionals in the Institute. The Committee is of the opinion that shortage of staff in both the campuses of the Institutes may lead to many Departments being non-functional at CNCI. The Committee, accordingly, recommends the Ministry of Health and Family Welfare to ensure that adequate staff is made available at the Institute vis-à-vis sanctioned posts on priority.**

**3.10.5 The Committee further notes that CNCI is one of the 25 Regional Cancer Centres in India and was envisaged as a cutting-edge cancer research centre, however, the Institute must take effective steps to expand its activities in basic and clinical research so as to draw conclusion out of translational cancer research.**

**3.10.6 The Committee observes that Chittaranjan National Cancer Institute, Kolkata has started a 30 bedded palliative care or hospice. The Committee agrees with the suggestion of the Director, CNCI that there is need of more Government support on palliative care and hospice. The Committee recommends the Ministry to give more thrust on Palliative care and provide support on Government-aided homecare support. The Committee accordingly recommends the Ministry to make continuous efforts for development of CNCI into a referral centre for Palliative care to all cancer care Institutes of Eastern India.**

**3.10.7 The Committee further recommends the Ministry to incorporate telemedicine services from the Primary Health Centers to the District/ Sub-divisional hospitals to the referral hospitals. The Committee is of the opinion that proper linkages between the PHC and Cancer Care Centres is missing. As a result, many of the referred people skip receiving treatment. The Committee, therefore, recommends the Ministry to strengthen the existing referral mechanism which will not only ensure a robust treatment plan but also facilitate better documentation of cancer related data.**

### Case Study : Tata Memorial Centre

3.11 TMC, a grant in aid organization under the Department of Atomic Energy has been doing pioneering work in the area of cancer care, education and research. Over the past 80 years, it has established itself as the leading institution providing cancer care for patients from across the country. Registering close to 120,000 new patients and over 800,000 follow ups annually, it provides high quality evidence-based cancer care to patients from across the country regardless of socio-economic status, with over 60% of patients being provided high quality cancer care either free or at highly subsidized costs. Under the State Government of Maharashtra's Health Scheme, "Mahatma Jyotiba Phule Jan Arogya Yojana" and Central Government's Scheme, "Ayushman Bharat-Pradhan Mantri Jan Arogya Yojana", the Tata Memorial Hospital's performance is indicated as under:-

TATA MEMORIAL HOSPITAL PERFORMANCE – HEALTH SCHEME				
MJPJAY – STATE SCHEME				
TMH				
Year	Patient Treated Count	Count Of Cases	Preauth Approved Amount	Claim Paid Amount
2012	537	800	22165990	2109007
2013	1337	3652	66627180	56985895
2014	2705	9384	142746910	116896023
2015	2673	11512	140506550	134840308
2016	2999	13549	167154700	137855968
2017	2923	13666	156965410	132030536
2018	3045	16023	177169585	135447554
2019	2623	13988	151281645	139339508
2020	2676	10777	127430660	104065991
2021	3467	17319	197110475	147321408
<b>Grand Total</b>	<b>24985</b>	<b>110670</b>	<b>1349159105</b>	<b>1106892198</b>

AB-PMJAY – CENTRAL SCHEME				
TMH				
Year	Patient Treated Count	Count Of Cases	Preauth Approved Amount	Claim Paid Amount
2019	640	1388	22294580	13676700
2020	336	956	13812252	12597502
2021	559	2637	35566000	26040910
2022	49	181	2645750	2698000
<b>Grand Total</b>	<b>1584</b>	<b>5162</b>	<b>74318582</b>	<b>55013112</b>

3.11.1 TMC also is the centre for cancer education in the country and trains over 150 students every year in various aspects of cancer including surgical, medical and radiation oncology. ACTREC is the research wing of TMC and houses several cancer researchers working towards unravelling the biology, causes and management of cancer. In addition, TMC has now expanded to seven other hospitals located in Varanasi (two), Guwahati, Sangrur,

Visakhapatnam, New Chandigarh and Muzaffarpur. It is expected that TMC will treat over 150,000 new patients with cancer annually by the year 2025.

3.11.2 In the meeting held with the representatives of TMC in Mumbai, the Committee was informed that this Distributed model will minimize patient migration. Under the hub and Spoke Model, comprehensive cancer centres as hubs will be capable of treating all cancers, including complex care. The Committee was also given to understand that the spokes connected to the central hub will be capable of treating common and less complex cancers. The expected cancer burden per 4 crore will be 40,000 (55,000 in 2035). One hub can be created in every state / every 4 (5.2 in 2035) crore population. It will be a 300 bedded facility and approximately Rs 700 crores capital will be required. The annual running costs would be Rs 110 to 120 crores. The Committee was further informed that the expected cancer burden per 1 crore is 10,000 (14,000 in 2035). One spoke may be created in every 1 (1.3 in 2035) crore population. It will be a 100 bedded facility and approximately Rs 380 crores capital will be required. The annual running costs would be Rs 35 to 40 crores.

3.11.3 Tata Memorial Centre and the National Cancer Grid is involved in several joint projects at the National and International levels. The NCG resource-stratified evidence-based management guidelines work towards uniformity of care by linkages to the AB-PMJAY scheme, several potentially practice-changing clinical research studies are underway with participation from several cancer centres and research institutions. Internationally, TMC collaborates with the National Cancer Institute, US, Princess Margaret Cancer Centre, King's College London, National Cancer Center Japan, the International Agency for Research on Cancer and the International Atomic Energy Agency. Additionally, basic scientists at ACTREC have several international collaborations under joint funding schemes such as Indo-UK, IndoGerman, Indo-US, and others. They also have joint research collaborations with many Indian institutions such as IIT Bombay, IISER, IISc, and others.

3.11.4 Tata Memorial Hospital is offering the highest level of cancer care to the poorest of the poor without any service charges. The duration of cancer treatment may vary from one to six months depending on the type and stage of cancer.

3.11.5 Tata Memorial Centre has a system wherein 60% of patients are treated either free or at highly subsidized costs, while 40% of patients are "private" patients who pay for their care. The revenue generated from the private patients goes a long way to meeting much of the routine expenditure incurred by the hospital, thereby, decreasing the fund demand from the Government.

3.11.6 TMC further submitted that regular training and continuing medical and nursing education (CME and CNE) are offered throughout the year by TMC, including specialized trainings like palliative care, Central Venous Access Device training, stoma clinic for nurses; workshops in cancer surgery, radiation planning and delivery etc

**3.11.7 The Committee commends the Tata Memorial Centre for providing outstanding service through evidence based practice of oncology and guiding the National Policy and strategy for cancer care. The Committee is assured that comprehensive cancer centers under the hub and spoke model will facilitate decentralization of cancer care. The Committee appreciates the expansion of TMC to seven hospitals located in Varanasi (two), Guwahati, Sangrur, Visakhapatnam, New Chandigarh and Muzaffarpur. The Committee accordingly recommends the Ministry of Health and Family Welfare and Department of Atomic Energy to indentify the probable hubs and spokes and expedite the creation of hubs and spoke under the guidance of TMC.**

**3.11.8 The Committee appreciates the TMC model of revenue generation that reduces the dependence on the Government for funds. The Committee notes that nearly 60% patients receive highly subsidized or almost free treatment and rest are private patients who pay for their care. Cancer treatment is financially draining and needs specific intervention on the part of the Government. The Committee accordingly believes that the Government may explore replicating the TMC model of revenue generation in other Cancer Institutes.**

**3.11.9 The Committee finds that TMC receives financial support from various government and non - government organizations to look after the needs of accommodation of the poor cancer patients. Taking a clue from the TMC Model, the Committee recommends the other Institutes to explore mobilizing the finances through philanthropic sources including Corporate Social Responsibility (CSR).**

**3.11.10 The Committee believes that the costs for cancer treatment can be further brought down by group negotiation for construction activities, equipment, drugs, and consumables. The Committee appreciates the efforts of TMC in this regard and recommends TMC to continue sharing its rate contract with other State Governments who can avail the benefits of the negotiated prices by TMC.**

#### **National Cancer Institute, Jhajjar**

3.12 In the Committee meeting held on 28<sup>th</sup> June, 2022, the Head, National Cancer Institute, Jhajjar submitted that NCI, Jhajjar, is campus of All India Institute of Medical Sciences. There are nearly more than 10,000 new cancer cases at the main campus in All India Institute of Medical Sciences and at the NCI together. He further submitted that there are currently more than 1.3 lakhs of people, old and new, who come for follow up. There are nearly 150 faculty members in the field of Oncology in both the campuses.

3.12.1 He further submitted that in the last two years, because of Covid, there were a lot of interruptions, but in the last six months, the situation has improved. The OPD is fully functional in NCI Jhajjar and all the facilities have started. NCI Jhajjar has also a 800-bedded facility which is called *VishramSadan*. However, transportation facility from the main campus to NCI is poor.

3.12.2 Head, National Cancer Institute, Jhajjar also submitted that conducting unnecessarily too many investigations also increases the cost of cancer treatment. There is a need to devise a method where only essential investigations are carried out. There is an increase in expensive tests such as molecular tests, genetic tests. The Government must take some measures to cut-down the cost and conduct cost-effective analysis of some of these investigations to see whether these are really necessary and whether they are finally impacting the quality of life for these people.

3.12.3 Similarly, the follow-up is also necessary. However, for each follow-up, a lot of centres will do PET scan, CT scan, which further increases the cost. There is a need to examine the patient's history and do minimum investigations rather than doing PET scan every three months or every four months. For cancer treatment, there are now some generic molecules or biosimilar molecules which have reduced the cost but there are still many new drugs where development of generic and the biosimilar molecules is still needed. So, the need of the hour is to do more research and development in the generic molecules in some of the newer patented, expensive drugs which can be made in the country; and will eventually reduce the cost of the treatment.

3.12.4 According to him, the major issue in the country is that almost 75 per cent of the cancer patients come to the hospitals at the advanced stage of disease. Unnecessarily, giving very intensive treatment to them jeopardizes their life. Therefore, there is a need to develop some protocols which are simpler, oral. People need not stay in the hospitals in the bigger cities rather the treatment can be taken at home. So, some of those protocols, which is called 'metronomic therapy' or 'oral therapy' can be developed.

3.12.5 The cost-effective analysis of some of these protocols are being done for advanced disease has to be done. The Head, NCI suggested that the Government should create a national expert kind of a body for this purpose. Similarly, the hospitals can be ranked based on the quality of the care which they are providing, based on the cost-effectiveness of the treatment which they are providing and many other parameters which can be taken for this purpose. It can really help to reduce the cost and bring in some of these innovative protocols.

3.12.6 There is also a need to publish papers on long-term follow-ups as to what really happened to the patients after five years, after ten years, after twenty years of treatment. Such long-term research on long-term outcomes, especially, on the effect of surgery, effect of chemotherapy, effect of radiation therapy in the country must be encouraged.

3.12.7 Another major concern is the radiation treatment cost. The cost of radiation therapy is Rs. 750 in All India Institute whereas the cost in a corporate hospital is from Rs. 1 lakh to Rs. 2 lakh or even more than this. Another major issue comes with the recurrent disease, the recurrent cancer, and again the cost of the treatment is enormously high. When the cancer comes back, people really use very expensive protocols. On the Palliative Medicine front, the NIC, Jhajjar really has done very good work, and now it has been designated as the WHO centre for next five years.

3.12.8 SWOT analysis of National Cancer Institute, Jhajjar:

<b>Strengths</b>	<b>Weakness</b>
<ul style="list-style-type: none"> <li>(i) State of Art Infrastructure for care of patients</li> <li>(ii) Availability of adequate number of Hospital beds (700), OT's, LINAC's, etc.</li> <li>(iii) Availability of full spectrum of cancer care under one roof including Medical Oncology, Surgical Oncology, Onco-Anaesthesia, Radiation Oncology, Nuclear Medicine, Lab Oncology, Radiology, etc.</li> <li>(iv) Availability of robotic core laboratory for routine blood investigations</li> <li>(v) Mentoring &amp; Leadership by best faculty and staff from AIIMS, New Delhi</li> <li>(vi) Focus on translational research and adequate space for research facilities</li> <li>(vii) Sufficient availability of staff accommodation</li> </ul>	<ul style="list-style-type: none"> <li>(i) Non-availability of in-house pathology, microbiology &amp; molecular oncology investigations (these are currently done at AIIMS, New Delhi)</li> <li>(ii) In-adequate manpower sanctions for certain categories like residents, senior residents, Senior Nursing Officers, ANS, DNS, Physiotherapists, Pharmacists, etc; Administrative Staff like Store keepers, LDC, UDC, etc.</li> <li>(iii) Inability to recruit staff at all levels as recruitment rules of AIIMS for certain posts only allow filling of vacancy by promotion for which eligible candidates are not always available or willing to go to Jhajjar</li> </ul>

Opportunities	Threats
<p>(i) There is a huge requirement of tertiary level cancer care facilities in India with cancer disease burden increasing everyday</p> <p>(ii) Certain cancer treatment options like Radiotherapy are available in very limited numbers in even private sector</p> <p>(iii) There are very few Cancer Institutes in India focusing on translational research in India specific cancers which is NCI's primary mandate</p> <p>(iv) NCI has collaborated with the best cancer Institute's globally like NCI-USA</p> <p>(v) NCI is installing PROTON Therapy which will be the 1<sup>st</sup> in a public hospital</p> <p>(vi) There is adequate space &amp; infrastructure available at NCI-Jhajjar and majority of cancer services currently offered at AIIMS, New Delhi can be shifted to NCI-Jhajjar. This will result in optimal utilization of space and facility at NCI-Jhajjar and will reduce waiting list at AIIMS for not-only cancer patients but other patients as well</p>	<p>(i) Road Connectivity of NCI-Jhajjar from Delhi &amp; Gurgaon is poor</p> <p>(ii) There is very limited availability of public transport to/from NCI-Jhajjar from various public transport hub points in Delhi / Gurgaon which makes it difficult for patients to commute</p> <p>(iii) Social infrastructure like schools, shopping areas, recreation space, parks, etc. around NCI-Jhajjar is very limited which makes it very difficult to attract young talent to NCI-Jhajjar <i>vis-a-vis</i> to AIIMS, New Delhi</p> <p>(iv) The land area around NCI-Jhajjar is unregulated rural land thereby allowing mushrooming of illegal shops including wine shops</p> <p>(v) Dr BRAIRCH at AIIMS, New Delhi is also offering a similar spectrum of services with same cadre of faculty &amp; staff and patients often prefer to go to AIIMS Delhi <i>vis-a-vis</i> coming to NCI-Jhajjar due to distance</p>

**3.12.9 The Committee notes that NCI-Jhajjar has been envisaged as an apex cancer treatment and research facility by the Ministry, however, the Institute lacks the facilities of in-house pathology, microbiology & molecular oncology investigations. The Committee strongly recommends the Ministry to make these services functional in NCI at the earliest and reduce its dependence on AIIMS, New Delhi.**

**3.12.10 The Committee finds that there is shortage of healthcare workforce in the Institute which has a grave impact on the functioning of the Institute. The Committee accordingly recommends the Government to ensure that adequate number of doctors and specialists are made available along with the administrative staff. The Ministry must expedite the recruitment for residents, senior residents, Senior Nursing Officers, ANS, DNS, Physiotherapists, Pharmacists as well as the other administrative staff.**

**3.12.11 The Committee takes into consideration the submission of the Ministry that there is adequate space & infrastructure available at NCI-Jhajjar and majority of cancer services currently offered at AIIMS, New Delhi can be shifted to NCI-Jhajjar. The Committee, accordingly, recommends the Ministry of Health and Family Welfare to explore transferring certain facilities at NCI so that the waiting list at AIIMS Delhi is reduced.**

**3.12.12 The Committee notes that the transportation facility to the Institute is very poor and it takes a lot of time for the people to go from main campus to the NCI. The**

**Committee, accordingly, recommends the Ministry to make proper transport arrangements and ensure proper connectivity around the area.**

**3.12.13 The Committee believes for ensuring the recruitment of young talent in NCI-Jhajjar, the Ministry will have to take effective measures and develop adequate social infrastructure like schools, shopping areas, recreation space, parks, etc. around NCI-Jhajjar. The area will have to be made more habitable and attractive so that people willingly join the Institute. The Committee accordingly recommends the Ministry of Health and Family Welfare to develop the infrastructure around NCI in coordination with the State Government and also start certain financial incentive package for the staff recruited in NCI.**

**3.12.14 The Committee draws the attention of the Ministry of Health and Family Welfare to ensure that all the weaknesses related to the working of NCI are overcome and specific interventions are made to ensure proper operationalization of the Institute by adopting guiding principles of the management by objectives.**

**3.12.15 The Committee recommends the Ministry to devise a rating mechanism for the hospitals on the quality of care, cost-effectiveness of the treatment provided and other relevant parameters. The Committee further believes that an assessment of various treatment outcomes out of all the available treatment options in Modern Medicine is also important to improve the Standard Treatment Protocol and patient outcome. The Committee accordingly recommends the Ministry to conduct long term research on long term outcomes and follow ups on impact of treatment on patients, especially from the effect of surgery, effect of chemotherapy and effect of radiation therapy on patients.**

### **Regional Cancer Centre (RCC), RIMS, Manipur**

3.13 In 2006, Radiation Oncology Department at Manipur was upgraded to Regional Cancer Centre, Manipur, RIMS, Imphal. The Department had been functioning as an independent department for more than 30 years in the state. Since then the department has been shouldering the responsibilities of cancer care service not only for the state of Manipur but also for other states like – Mizoram, Nagaland particularly. A proposal had been submitted by RIMS to the Ministry for setting up of TCCC at RIMS, Imphal, under the scheme National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) on 14th July 2014 duly recommended by the Govt. of Manipur. The existing RCC without any funding from the Ministry since 2006 is in dire need of development in many technical aspects of modern cancer treatment. Many of the equipments in the Radiation Oncology Department which are being used to treat cancer patients is almost out dated and they need replacement with modern state of the art equipments. For academic purposes, RIMS has been sending graduate students to bigger centres like BCCI, Guwahati or TMH, Mumbai every year. Unfortunately essential departments like Surgical Oncology, Nuclear Medicine and Medical Oncology are not available in the RCC. Radiation Oncologists are practicing chemotherapy due to non-availability of medical oncologist and general surgeons who underwent short term training in surgical oncology are operating only few cancers in the RCC.

3.13.1 The Department itself is imparting PG (MD) course in Radiation Oncology as the first Department in North East including Assam since 2001. Number of PG intake is 4 PG students per year – 50% students from North East States, another 50 % come from All India Quota (from the rest of the country). The PG (MD) course is recognized by MCI/NMC. So far more than 56 Doctors had been awarded MD (Radiation Oncology) from many states of

the country. Now all of them are working across the country as faculty in medical Colleges, as Clinicians in many reputed cancer hospitals. Even, few students went abroad after passing MD for job. RCC has been conducting training programme of doctors, nurses and community health officers related to the cancer patient care in Primary Health Centres (PHC)& District hospitals in the field of day care chemotherapy, nursing care of cancer patients and palliative care of terminal cancer patients.

3.13.2 As per the available information, National cancer control programme was implemented by Government of Manipur in the form of NPCDCS. Opportunistic screening of Non-communicable disease ( NCD) under NPCDCS started in 2016. Under the National Health Mission, Sub-centres and PHC started population based screening programme of few cancers of oral cavity, breast and cancer cervix since 2018. Department of Radiation oncology also conducted health camps in the peripheral rural area

3.13.3 Ongoing Cancer registry at RCC include PBCR ( Population based cancer registry) Country wide registry of cancer. RIMS is also one of the centre since 2003 - Population based cancer survival on cancer of breast, cervix and Head and neck since 2017 - Hospital base cancer registry since 2015 - Pattern of care and survival studies on head and neck, breast and cervical cancer since 2015

3.13.4 ICMR ongoing projects

- i. Monitoring survey of cancer risk factors and health system response in North east region , Manipur ( 2020-2021)
- ii. Analysis of the prevalence of non habitual oral squamous cell carcinoma in young adults and its association with human papilloma virus in North East India with special reference to Manipur
- iii. Prevalence of Oral premalignant lesions (OPML) and its associated factors in Manipur

3.13.5 The Hub & Spoke Model, could be adopted in Manipur, Existing RCC at RIMS may be upgraded to a cancer hospital as Hub & District Hospital as Spoke for comprehensive care for Prevention, Diagnosis, Research & Affordability of cancer treatment in the state. District hospitals may be upgraded with addition of one Oncology wing. In the Cancer hospital, there may be provision for opening of different departments like Surgical Oncology, Medical Oncology, Nuclear Medicine, Palliative Care and Preventive Oncology. Opening of Post graduate course and short term courses in the respective departments may help in developing human resource for cancer management across the country.

**3.13.6 The Committee notes that Manipur has one of the highest incidences of cancer in the North Eastern area. M.D. in radiation oncology was started in 2001 in RIMS Manipur and the Institute was upgraded to Regional Cancer Centre in 2006. The Institute was envisaged as a specialized cancer centre, however, the Committee observes that RIMS has very limited facility in terms of infrastructure and trained manpower. Cancer Patients from the North Eastern Region have to go to other parts of the country for cancer treatment.**

**3.13.7 The Committee notes that irrespective of RIMS Manipur serving as a RCC, Departments of Surgical Oncology, Medical Oncology and Nuclear Medicine are non-functional in RIMS. The Committee also observes that RIMS had applied for up gradation to Tertiary Cancer Care Centre in 2014 and the approval has not yet been received. The Committee is appalled to note that the Institute does not even have the**

facilities of PET scan. The Committee strongly recommends the Ministry to ensure that the Institute starts functioning as a Tertiary Cancer Care Centre and various Departments of Oncology are made functional in the Institute along with the desired number of human resources.

3.13.8 The Committee believes that for strengthening of Institutional arrangement, the key concern areas as highlighted by RIMS must be adequately addressed. The Committee in its 126<sup>th</sup> Report had also examined the status of vacancies in RIMS and noted that the patient load has increased many fold in the last 20 years. However, the sanctioned strength of faculty has remained the same. The Committee reiterates that the Ministry must take concrete steps for creation of new Posts and expedite the recruitment process to fill up the vacant posts.

### **Changes needed in the Institutional Framework**

#### **Need for a Centralised Public Health Research Institute**

3.14.1 The Committee observes that India has an extensive network of Public health Institutions from the Health Wellness Centres to the Tertiary care Centres. However, there is a big scope for upgradation and the delivery of health care services at these Centres. The Committee further notes that ICMR is the National apex Research body that conducts research on various public health issues. The Committee however feels that there is a great need to utilise the outcomes of the research findings by ICMR and other Research Bodies in institutionalizing a better framework for cancer care and its management. The Committee notes that the States lack the Technical expertise to formulate specific cancer care policies in the State. The Committee finds that the rates of cancer incidences are different across States. Some form of cancer is more prominent in some regions whereas some States report lower incidences of the same cancer. The Committee strongly feels that a one size fits all approach cannot be adopted if the cancer incidence is to be controlled. The Committee therefore strongly recommends the Ministry to ensure that the National Research Bodies to the likes of ICMR collaborate with the States in designing State specific institutional framework across the country.

#### **Region-wise equitable distribution of Government-run Cancer Centres**

3.14.2 The Committee is of the view that there is an urgent need to strengthen the existing cancer centres across the States/UTs on priority basis. The Government, through its various initiatives such as the National Cancer Grid, is working towards providing uniform cancer care across the country. The Committee however feels there is a need to expand the network of cancer centres in the country. It is a well established fact that cancer care is financially draining on the patient's family and drives families to poverty. The Committee expresses its concern that there are many regions which remain deprived of modern cancer care. The Committee accordingly believes that the Government must establish additional Government cancer centers so that affordable high quality cancer services are provided to the general public. The Committee reiterates that the Government must ensure the completion of the envisaged State Cancer Institute (SCT) and Tertiary Cancer Care Centre (TCCC). The Committee commends the partnership between Tata Memorial Centre and State Governments and recommends the Ministry to encourage such collaboration across the country. The Governments must explore public-private partnerships for establishing more Cancer

Care Centers and adopt best practices and provide standardized treatment protocol in these Centers.

**3.14.3** The Committee also recommends the Ministry to create a platform where these Institutions can interact and learn from the best practices followed in each Institute on the novel initiatives taken for making cancer care affordable. Such a platform will also facilitate a comprehensive assessment of the affordability as well as the efficacy of the treatment protocols.

#### **Price negotiation**

**3.14.4** The Committee takes into account that anti cancer drugs as well as equipments are very expensive and the Cancer Centers would find it difficult to negotiate competitive prices with equipment manufacturers and the pharmaceutical industry. The Committee has also been informed that the exploiting the volumes of individual cancer centres, the NCG has negotiated with pharmaceutical companies for high value cancer drugs. By aggregating the demand from many centres, the NCG worked on a solution wherein “price discovery” of commonly used, high-value items are negotiated with industry, thereby passing on the benefits to member centres and onwards to patients. Using transparent policies for tendering and a web-enabled e-tendering platform, this initiative has brought down current costs of cancer care significantly (average of 55% discount on MRP) while maintaining the quality of drugs.

**3.14.5** The Committee believes that Group negotiation for cancer drugs would facilitate better price for the anti cancer drugs by increasing the bargaining power. The Committee accordingly recommends the Government to take measures to encourage such group negotiation for cancer drugs through a transparent central tendering platform. The Committee notes that such group negotiations by TMC have led to a 20 to 80 % discount on cancer drugs. The Committee further recommends the Government to extend such price negotiation to equipment & consumables also.

#### **Human Resource Forecasting & Planning**

**3.14.6** The Committee expresses concern over the lack of adequate manpower to make the cancer centres fully operational. In the absence of specialized healthcare force, many super specialities remain defunct even after the establishment of the physical infrastructure. The Committee, accordingly, recommends the Ministry of Health and Family Welfare to take effective measures to fill the vacant posts *vis-à-vis* the sanctioned strength in these Cancer Care Units. To avoid such delays in making the centres fully operational, the Ministry must make manpower provision at the time of sanctioning a project. The Committee is of the view that the State Governments must also play an active role in ensuring that the manpower in State-run Cancer Institutes is adequate. The Committee observes that very few institutions conduct technical courses that produce paramedics and technicians that can take care of increasing load of cancer patients. The Committee, therefore, recommends the Ministry to increase such courses as the trained manpower is fundamental to providing value-added-services to the patients which will help improve their quality of life.

**3.14.7** The Committee appreciates the Shared Hospital Income (SHI) scheme of Tata Memorial Centre wherein approximately 12 to 15% of overall hospital income is shared amongst medical staff. The Committee recommends the Ministry to implement similar Scheme across other cancer centres to retain qualified staff.

## **Inadequate Insurance Coverage**

**3.14.8 The Committee notes that insurance companies bank on maximization of profit and all cancer treatments are not covered in the health insurance scheme. The Committee further notes that as per current IRDA regulations, most cancer survivors cannot avail of health insurance even for non-cancer related ailments. It has been brought to the notice of the Committee that many cancer survivors were not able to get insurance cover during the COVID pandemic. The Committee accordingly recommends the Ministry to take up and pursue vigorously with the IRDA to revise the insurance regulations to ensure that the cancer patients are not denied insurance benefits.**

**3.14.9 The Committee further notes that innovative health insurance packages are required for ensuring adequate financial coverage for cancer treatment. Various stakeholders have also highlighted on the need for inclusion of middle class in Government Health Schemes especially for Cancer treatment and rare diseases that necessitates high financial expenditure. The Committee notes that the middle class remain out of the ambit of Health Insurance Schemes such as AB-PMJAY and bear the expenses from their own pocket. The Committee accordingly recommends the Ministry of Health and Family Welfare to examine in the right earnest and expand the list of beneficiaries under AB-PMJAY so that middle class can also avail free treatment for critical illness such as cancer. This can go a long way in saving the families of cancer patients of middle class from going into penury.**

### **Need for focused approach to Pediatric cancer**

3.14.10 The Indian Cancer Society estimates that each year, as many as 50,000 children and adolescents aged 0 to 19 years will be diagnosed with cancer in India. Childhood cancers have a very good prognosis when treated in dedicated centres.

3.14.11 Six states are expected to account for over 50% cases of pediatric cancer cases in India by 2024 (Rajasthan, WB, Maharashtra, MP, Bihar, UP). In order to avoid constant travel over large distances, many rural parents give up on their source of income and move to cities for treatment of their cancer-stricken children. The table below shows the top 10 districts from which the families staying at St Judescentres hail from.

<b>S. No</b>	<b>District</b>	<b>State</b>	<b>Number of cases</b>
1	Hooghly	West Bengal	70
2	South 24 Parganas	West Bengal	66
3	North 24 Parganas	West Bengal	63
4	Jalgaon	Maharashtra	62
5	Ahmednagar	Maharashtra	62
6	Nadia	West Bengal	61
7	West Medinapur	West Bengal	55
8	Solapur	Maharashtra	52
9	Alwar	Rajasthan	50
10	Buldana	Maharashtra	48

3.14.12 St. Jude India Childcare Centre submitted that as per estimates, by the year 2024, around 32,000 pediatric patients undergoing cancer treatment will require “home away from home” support. These are children residing in rural areas and small towns who need to travel

to larger cities to avail treatment and would be unable to afford a place to stay. At present, the current capacity of HAH services for pediatric patients is estimated to less than 1,000 units across the country. In order to meet the estimated requirement by 2024, there is requirement of at least 10,000 units which is 10 times the current capacity.

**3.14.13 The Committee is deeply concerned about the anticipated increase in the number of pediatric cancer patients. The Committee feels that these young patients need all out support in terms of physical as well as financial resources from the State Government and Central Government to undergo quality cancer care treatment. The Committee notes that early diagnosis of pediatric cancer can greatly increase the chances of the success of treatment. The Committee accordingly recommends that the PHC must have trained health care professionals for early cancer detection and screening and be sensitive while handling children likely to be suffering from cancer. The Committee desires the Ministry to ensure that special insurance package for pediatric cancer covers the entire cost of treatment of the child suffering from cancer or even explore the possibility of including all children suffering from cancer under the Ayushman Bharat Scheme. Further the health personnel need to be trained/sensitized with respect to compassionate and quality care of these children.**

**3.14.14 The Committee observes that Home Away from Home facilities are not classified under Nursing Homes, clinics, Dharmshalas or hostels. The Committee is of the view that recognizing HAH as a separate category will help in the establishment of many such homes and ensure that the facilities operate under appropriate regulatory and legal framework. The Committee accordingly recommends the Ministry to make necessary changes and provide recognition to Home Away from Homes as a separate category.**

**3.14.15 The Committee notes that with the ever increasing burden of cancer in the country, there is an urgent need to review and upgrade the institutional framework for cancer care and management in the country. The Committee observes that despite Health being a State subject, the larger responsibility lies with the Union Government for formulating different Health Policies and National Level Programs and Schemes. The Committee further notes that the Central Government with greater pool of financial resources and stronger technical support system is better equipped to ensure robust implementation of the National Health Programs.**

#### **Strengthening the Institutional arrangement**

3.15 The Committee has been given to understand that the following steps may be taken for further strengthening the Institutional framework for Cancer Care and Management:-

- i. Strengthening of every District hospital with Oncology Wing (Surgery, chemotherapy & palliative care)
- ii. Upgradation of the existing RCC to Cancer hospital
- iii. More awareness programme on utilization of central financial assistance to public & doctors for cancer treatment
- iv. Opening of cancer patient accommodation and transportation centres in every district under Government support or NGOs.
- v. Increased awareness among public and health workers about certified generic anti cancer drugs
- vi. Increased availability of certified generic anti cancer drugs in the market.

**3.15.1 The Committee accordingly recommends the Ministry to strengthen every District hospital with Oncology Wing and conduct more awareness programme on utilization of central financial assistance to public & doctors for cancer treatment. The Ministry must also ensure that more cancer patient accommodation and transportation centres in every district are opened. The Ministry must also conduct specific programs for increased awareness among public and health workers about certified generic anti cancer drugs.**

**3.15.2 The Committee is of the opinion that Public Health Programmes aimed at Cancer Control are crucial for improving the cancer burden in the country. A National Cancer Control Plan that is aimed at adopting evidence based strategies for cancer prevention, early diagnosis, treatment and palliative care and implementing the National Cancer Policy across the States forms the keystone in developing the desired Institutional Framework for Cancer Care and Management.**

## CHAPTER-IV

### ACCESSIBILITY & AFFORDABILITY OF CANCER TREATMENT

4.1 Cancer is diagnosed by various specialties e.g., Biochemistry, Pathology, Radiology, Nuclear Medicine and by the specialists of concerned areas, for example Neurologist/ Neuro Surgeon for brain, Gynaecologist for Cervical, Uterus & Ovary Cancer, Gastrointestinal surgeon for liver and intestine cancer, Orthopaedics for bone cancer etc. The treatment requires surgeon of concerned specialties e.g., General Surgeon, ENT Surgeon & others. The other modalities are chemotherapy, radiotherapy and palliative care. The cost of treatment of Cancer depends on various factors that *inter alia*, include the stage of diagnosis, type and site of cancer, type of treatment etc. The prerogative of using any modality/protocol/drug in cancer patients is of the physician, the institution concerned, and the available Operational Guidelines (OG) are only indicative/suggestive and not mandatory.

4.1.1 Cancer is a disease that develops when cells in your body divide at a faster rate than normal. These abnormal cells grow into a lump or tumor. Most cancers have four stages. The specific stage is determined by a few different factors, including the size and location of the tumor:

- **Stage I:** Cancer is localized to a small area and hasn't spread to lymph nodes or other tissues.
- **Stage II:** Cancer has grown, but it hasn't spread.
- **Stage III:** Cancer has grown larger and has possibly spread to lymph nodes or other tissues.
- **Stage IV:** Cancer has spread to other organs or areas of your body. This stage is also referred to as metastatic or advanced cancer.

4.1.2 Though stages I through IV are the most common, there is also stage zero. This earliest phase describes cancer that is still localized to the area in which it started. Cancers that are still in stage zero are usually easily treatable and are considered pre-cancerous by most healthcare providers. Once the medical team has diagnosed, the team will design a personalized treatment plan based on their findings. Cancer Treatment is the treatment method of using chemotherapy, radiation therapy, medication therapy, surgery either to cure, treat, control, or reduce the symptoms of any type of cancer. With the help of chemotherapy, radiation, and surgery, Cancer Treatment can remove, kill or damage the cancer cells in a certain area of the body. Cancer Treatment can control cancer spread or damage the cancerous cells and prevent them from coming back.

4.1.3 The Committee has been informed that cancer treatment may include the following methods:

- (i) **Chemotherapy-** One of the most common cancer treatments, chemotherapy uses powerful drugs to destroy cancer cells. Chemotherapy may be given through an IV or in pill form.
- (ii) **Radiation Therapy-** This treatment kills cancer cells with high dosages of radiation. In some instances, radiation may be given at the same time as chemotherapy.
- (iii) **Surgery-** In some cases, the surgeon can surgically remove the tumor.

- (iv) **Hormone Therapy-** Sometimes hormones can block other cancer-causing hormones. For example, men with prostate cancer might be given hormones to keep testosterone (which contributes to prostate cancer) at bay.
- (v) **Biological response modifier therapy-** This treatment stimulates the immune system and helps it perform more effectively. It does this by changing the body's natural processes.
- (vi) **Immunotherapy-** Sometimes called biological therapy, immunotherapy treats disease by using the power of the body's immune system. It can target cancer cells while leaving healthy cells intact.
- (vii) **Bone Marrow transplant-** Also called stem cell transplantation, this treatment replaces damaged stem cells with healthy ones. Prior to transplantation, the patient undergoes chemotherapy to prepare the body for the process.

4.1.4 While the responsibility for cancer care in the Public Health Institutions lies with the Department of Health and Family Welfare, the Department of Pharmaceuticals is mandated to regulate issues related to pricing and availability of medicine at affordable prices, Research and Development protection of intellectual property rights and international commitments related to pharmaceuticals sector. Major segments of Indian Pharmaceutical Industry include generic drugs, OTC medicines, bulk drugs, vaccines, contract research & manufacturing, biosimilars and biologics. Because of the low price and high quality, Indian medicines are preferred worldwide, thereby making the country the "*pharmacy of the world*".

4.1.5 The Department of Pharmaceuticals strives to ensure the availability of Affordable Medicines including Anti-cancer medicines using the Departmental scheme of *PM-BJP*, the scheme for making the quality generic medicines available at affordable prices to all especially to the Poor and the deprived ones through the dedicated Jan Aushadhi outlets. The department also ensures the affordability of essential medicines, including Anti-cancer medicines, through Price monitoring mechanism of National Pharmaceutical Pricing Authority (NPPA). Treatment of cancer is either free or subsidized in the Government Institutions. Further, financial assistance is provided to poor patients for their cancer treatment under the Health Minister's Cancer Patient Fund component of the Umbrella scheme of the Rashtriya Arogya Nidhi (RAN).

#### **National Pharmaceutical Pricing Authority (NPPA)**

4.2 The National Pharmaceutical Pricing Authority (NPPA), an independent body of experts in the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers. The functions of NPPA, *inter-alia*, include fixation and revision of prices of scheduled formulations under the Drugs Prices Control Order (DPCO), as well as monitoring and enforcement of prices. During the Committee's meeting held on 8<sup>th</sup> July, 2022 the Chairperson of NPPA informed the Committee that the DPCO 2013 provides following three primary mechanisms for fixing or regulating the pricing of drugs:-

- (a) The ceiling price of drugs is fixed under Schedule-I of DPCO which forms the part of NLEM. Ceiling prices means, any manufacturer is free to price up to that ceiling level, however, the manufacture is definitely free to fix his price even below that but he cannot cross ceiling as far as fixing the price of drug is concerned. The objective is to bring down the price.
- (b) The second methodology is retail price fixation for new drugs. New drugs are those which have some scheduled component in that, because scheduled drugs have a ceiling price, therefore, it was thought that new drugs which have

scheduled component should also have some sort of price control. So, retail prices for new drugs are also fixed by the NPPA based on the methodology prescribed under DPCO.

- (c) The third category is the non-scheduled drugs which are not part of NLEM. As per the DPCO, any manufacturer is free to fix the price of a drug as per his cost of production but the manufacturer cannot increase the price of a drug by more than 10 per cent in a particular year. A manufacturer is at liberty to fix the Maximum Retail Price (MRP) of a non-scheduled formulation branded or generic launched by it, however, as per the DPCO, the manufacturers of non-scheduled formulations are not allowed to increase the MRP of such formulations by more than 10% per annum.

4.2.1 The Government has notified National Pharmaceutical Pricing Policy, 2012 (NPPP-2012) with an objective to put in place a regulatory framework for pricing of drugs so as to ensure availability of required medicines “essential medicines” at reasonable prices. The NPP Policy essentially links the drug price regulation to essentiality and the regulatory framework for drug price control emanates from Section-3 of the Essential Commodities Act - 1955.

4.2.2 The key principles for regulation of prices in the National Pharmaceuticals Pricing Policy 2012 are Essentiality of Drugs, Control of Formulations prices only, and Market Based Pricing. The Department of Pharmaceuticals take the list of essential drugs, as notified by the Department of Health, and then work on it for the purpose of regulation under the DPCO. The National Pharmaceutical Pricing Policy provides only for control of formulation prices. Formulation means a particular strength of the drug, a particular strength is called one formulation. Earlier DPCO had a system where they used to control the prices of bulk drugs also, but this DPCO 2013 only allows control of formulation prices while bulk drug prices are currently market driven. The DPCO is notified by the Department of Pharmaceutical under the NPPP. The DPCO, 2013 under NPPP provides for calculation of prices of drugs, including ceiling and retail prices, on the basis of market data. When the DPCO was promulgated, a methodology was prescribed under the DPCO wherein particular pricing data is to be collected for determination of price of a particular drug.

4.2.3 Responding to the Committee's query, in its meeting held on 8<sup>th</sup> July, 2022, as to why not the price of cancer drug are calculated on cost of production for value based pricing, the Secretary, the Department of Pharmaceuticals pleaded as under:-

*"Earlier, before DPCO, 2013, and the NPPP, 2012, the prices were fixed by NPPA based on the cost of production...why not going in for 'cost' and going in for 'market data'...in India, the strength lies in generic medicines. Generic drugs are not patented drugs. Therefore, their process of production is not standardized under a patent. The same product can be manufactured through different processes using different production technology. It, therefore, became difficult to fix the cost for a single drug which potentially can be manufactured through different technologies...it was something which was considered in 2012 and 2013 – that the market is a better reflection and a transparent reflection of the prices that are available... by that time, it was a competitive market. There are several brands of the same drug...in a multi-brand situation for almost every drug, it was felt that market-based pricing will give a better reflection of price, as it should be, rather than cost-based methodology...having challenges in identifying cost vis-à-vis specific technology."*

4.2.4 Based on the NPPP, 2012, the Government notified DPCO, 2013 on 15th May, 2013 in supersession of DPCO, 1995, the National List of Essential Medicines (NLEM), notified by the Ministry of Health & Family Welfare is adopted as the primary basis for determining essentiality and is incorporated in the First Schedule of DPCO, 2013 which constitutes the list of scheduled medicines for the purpose of price control. Ceiling prices of scheduled formulations are fixed based on 'market based data'. Price control is applied to specific formulations with reference to the medicine (active pharmaceutical ingredient), route of administration, dosage form / strength as specified in the First Schedule.

**(i) Ceiling Price Fixation under DPCO, 2013**

4.2.5 National Pharmaceutical Pricing Authority (NPPA) fixes the ceiling price of scheduled medicines specified in the first schedule of the Drugs (Prices Control) Order, 2013 [DPCO] in accordance with the provision of DPCO. All manufacturers of scheduled medicines (branded or generic) have to sell their products within the ceiling price (plus applicable Goods and Service Tax) fixed by the NPPA.

4.2.6 All the medicines specified in the National List of Essential Medicines 2011 (NLEM) were included in the First Schedule of DPCO, 2013 and brought under price control on notification of DPCO, 2013. These are the scheduled medicines. Under DPCO, 2013, prices of drugs are fixed on 'Market based pricing' methodology and it has been adopted in accordance with the principles outlined in the NPPP, 2012. The methodology of fixing a ceiling price of NLEM medicines, is worked out by adopting the Simple Average Price of all the brands having market share (on the basis of Moving Annual Turnover) more than or equal to 1% of the total market turnover of that medicine and then by adding a notional 16 % retailer's margin to the average arrived at, for working out the ceiling price.

4.2.7 Responding to the Committee's query about the reason or the basis for keeping a 16% retailer's margin as it appears to be very high to give a margin of 16% to the retailer, the Secretary, the Department of Pharmaceuticals stated as under:-

*"Way back in 2005, certain studies were done. At that time, different margins had been mooted. For retailers, a margin of either 15 per cent or 20 or 35 was mooted. In the DPCO, 16 per cent has been taken. If we make a comparison with any other line of business, even in our Government contracts, for example, where we provide contracts for contractors for building construction, etc., a margin of 10 to 15 per cent is provided, even though they are large contracts, sometimes in crores, whereas these are retailers. Their daily turnover may not be very high. So, 16 per cent appeared at that time to be a reasonable margin."*

4.2.8 The Schedule I of DPCO 2013 was revised to include National List of Essential Medicines (NLEM) 2015. The formulations are classified across 32 therapeutic groups and NPPA has fixed the ceiling prices of 890 formulations under DPCO, 2013 till 1<sup>st</sup> July, 2022. The therapeutic category wise details areas under, which includes 86 formulations of Anti-Cancer drugs.

**Categories of Medicines under which Ceiling Prices have been fixed**

Category	Number of Medicines	Number of Formulations
Anti-Cancer	44	86

Anti-TB	14	35
Anti-HIV	11	39
Anti-Diabetics	5	13
Cardiovascular	30	74
Other	254	643
<b>Total</b>	<b>358</b>	<b>890</b>

4.2.9 There are 44 medicines prescribed as anti-cancer medicines in Schedule-I of DPCO, 2013 under Sections 8.1, 8.2 and 8.3. NPPA has fixed the ceiling prices of these 44 anti-cancer medicines comprising of 86 formulations. The 86 formulations along with applicable ceiling price (excluding GST) is w.e.f. 01.04.2022. The prices are notified through Gazette Notifications which are also uploaded on NPPA's website at [www.nppaindia.nic.in](http://www.nppaindia.nic.in). The ceiling prices become operative and legally enforceable from the date on which the price is notified in the Gazette.

**4.2.10 The Committee observes that 16% margin for retailers in determining prices of the medicine under National List of Essential Medicines (NLEM) are too high as the same must have bearing on the price of the life saving medicines. The Committee is not in agreement with the argument of the Secretary, the Department of Pharmaceuticals that since a margin of 10 to 15% is provided in Government contracts or other line of business, therefore, 16% retailers margin stands rationale. The analogy between the retailers 16% margin and the profit margin of 10 to 15% margin in Government contracts or other line of business is absolute and out of context as the Government while providing healthcare services to the cancer patient should not be guided by the profit motive as in the case of the other business line. Being a welfare state, the Committee urges upon the Government to rationalize the retailers 16% margin in the interest of the patients who are struggling for their life. In case it is not possible to reduce retailers margin Government can subsidy to retailers or consumers.**

4.2.11 Pertaining to the Committee's query about the impact on the price of the drugs in next five years in case 10% annual increment in the price of the non-scheduled drugs is allowed to the manufacturer, the Secretary, the Department of Pharmaceuticals argued that annual limit of 10% increment does not mean to say that manufactures have to increase it by 10% and the increment may be of 2% or 5% but limit indicates that the increase cannot be more than 10%. The Secretary, mentioned the phenomena of price fixation of non-scheduled drugs as under:-

*"Because of competitive pressures, actual price increase is rarely 10 per cent...In the ceiling price, manufacturers are permitted an annual increase limited to the WPI. This year the WPI was high...When we did analysis, we found that over a period of about 8 years or so actual price increase in the drugs had been only between 2-4 per cent. Although there is a provision in the DPCO which allows, if required, to increase the price up to 10 per cent, but, in actual practice, because of market competitive pressure, this does not take place. It does take place in a few cases...where we have high growth in input prices, particularly of APIs or of packaging material...during the entire two years of COVID pandemic, freight prices had gone up, container shipping prices had gone up for those who are dependent on imported inputs. So, that is the time when this 10 per cent is entirely utilized. But, normally, market competitive pressures carry more weight than the available price increase permitted as per the DPCO. It is not to say that*

*everybody stays below 10 per cent and it is also not to say that every drug utilizes the entire 10 per cent."*

4.2.12 The Secretary further clarified that ceiling price during the current year was 10%, however, in the past when the wholesale price index was negative it was minus 6% and at one point of time it was 2%. In the last decade, when there was low inflation rates in the country the actual increase in the ceiling price of the drug have been somewhere around 3 to 4 % but to change it to that percentage is not correct because the department has adopted the WPI parameter and ceiling price and the reflection of WPI.

**4.2.13 The Committee takes into account that National Pharmaceutical Pricing Authority (NPPA) fixes the ceiling price of scheduled medicines specified in the first schedule of the Drugs (Prices Control) Order, 2013 [DPCO] in accordance with the provision of DPCO. All manufacturers of scheduled medicines (branded or generic) have to sell their products within the ceiling price (plus applicable Goods and Service Tax) fixed by the NPPA. As per the DPCO, the manufacturers of non-scheduled formulations are not allowed to increase the MRP of such formulations by more than 10% per annum.**

**4.2.14 The Committee observes that 10% annual increment in the price of the non-scheduled drugs is allowed to the manufacturer that gives undue liberty to the manufacturer to enhance the price of the non-scheduled drugs. The Committee, while taking into account the submission of the Secretary, the Department of Pharmaceutical, that over a period of about 8 years or so the actual price increase in the drugs had been only between 2 to 4%, recommends the Government to rationalize the annual limit of 10% increment to 5% annual increment in order to rescue the poor cancer patients and their family from the dipping into scourge of poverty. The Committee recalls the submission of the Secretary, the Department of Pharmaceuticals that due to market competitive pressure the actual price increase is rarely 10%, however, it is not to say that each manufacturer keeps the price of the drug below 10% and it is also not to say that every drug utilizes the entire 10% ceiling. The Committee, accordingly recommends the Government not to allow sweeping 10% annual increment ceiling, thereby giving the manufacturer the undue scope for "Profit Motive engineering /mongering" for skyrocketing the price of the life saving anti cancer drugs and thus compelling the patient's pressure on out of pocket expenditure thereby pushing them below the poverty line. The Committee, therefore, recommends the Government to have better approach/mechanism of regulation of anti cancer formulation/drugs.**

**(ii) Revision of Ceiling/Retail Price under Para 19 of DPCO, 2013: (Trade Margin Rationalization Approach)**

4.2.15 In case of extra-ordinary circumstances, Para 19 of DPCO, 2013 empowers the Government to fix the ceiling price or retail price of any drug for such period as it may deem fit in public interest. The mandate of NPPA is to ensure availability of drugs at affordable prices and it was noted that while ensuring affordability, access cannot be jeopardized and the lifesaving essential drugs must remain available to the general public at all times. NPPA capped the Trade Margin at 30% of MRP of select 42 Anti-Cancer non-scheduled formulations, recommended by Expert Committee of Ministry of Health & Family Welfare, under the 'Trade margin Rationalization Approach' vide order SO 1041(E) dated 27th February 2019. The Pilot has been taken up as Proof of Concept, invoking provision of paragraph 19 of DPCO, 2013, under extra-ordinary circumstances in public interest. Trade

margin means the margin from the first point of first sale to the final MRP of drug sold to the consumer. The Secretary, the Department of Pharmaceuticals clarified that 30% margin as taken in TMR approach is the margin for both, the distributor and the retailer because it is on the price to stockist, therefore, it covers two levels, the distributor as well as the retailer.

4.2.16 Under trade margin rationalization approach, the Maximum Retail Price [MRP] of 526 brands of anti-cancer medicines has been reduced by upto 90%. This move resulted in estimated annual savings of around Rs. 984 crore to the patients. As per data submitted by manufacturers, the MRP for 526 brands have been shown reduction up to 91%. Percentage wise reduction in prices of brands is as follows:

S. No	Slab-percentage reduction in prices	No. of Brands
1	75% and above	63
2	60% to 75%	167
3	25% to 50%	169
4	Up to 25%	127
5	<b>Total</b>	<b>526</b>

**4.2.17 The Committee expresses its concern over the determination of price of the medicine under Para 19 of DPCO 2013 through Trade Margin Rationalization Approach where NPPA caps the Trade Margin at 30% of MRP of Anti Cancer Non-Scheduled Formulation. It is being pleaded that 30% margin as taken in TMR approach is the margin for both the distributor and the retailer still the 30% Trade Margin under TMR mechanism appears to be mammoth price increasing factor of life saving anti cancer medicine. The Committee, therefore, persuades the Government to explore the scope for reducing trade margin under TMR mechanism of determining the price of anti cancer formulation to a rationale level in order to make cancer treatment more affordable and thus protect the patient from dwindling into financial hardship.**

**(iii) Affordable Medicines and Reliable Implants for Treatment (AMRIT)**

4.2.18 A novel initiative, was launched by the Ministry of Health & Family Welfare on 15<sup>th</sup> November, 2015 that aims to provide affordable life-saving medicines, other drugs and medical disposables for treatment of cancer and other diseases. The primary goal of AMRIT is to make available and accessible, at very affordable rates, all drugs, implants, surgical disposables that are not dispensed free of cost by the hospitals. The AMRIT programme is being implemented through Mini Ratna PSU HLL Lifecare Limited (HLL) which has been mandated to set up Pharmacies for major hospitals across the country to dispense the medicine. The first AMRIT centre was launched at All India Institute of Medical Sciences (AIIMS), New Delhi and now the AMRIT outlets have been open in major Government Hospital in cities. The AMRIT pharmacies stock nearly 2,200 drugs, surgical disposables and implants (including for cardiovascular, cancer and diabetes, stents etc.) that are offered at an average discount of 63 percent on medicines.

**4.2.19 The Committee appreciates the provision of AMRIT Scheme for ensuring affordable life saving cancer, cardiac drugs and medical disposables. The Committee hopes that the initiative under AMRIT will offer affordable drugs and medical implants at the ground level and will ease the burden of cancer patient, especially the underserved, in meeting the cost of drugs. The Committee desires that the implementing agency of AMRIT Scheme i.e. HLL Lifecare Limited should genuinely strive to the goal of the scheme in ensuring that no patient is deprived of life saving and other drugs for reasons of unaffordability. The Committee also recommends that HLL should open the AMRIT outlets in remote village areas, urban slums and tribal areas to ensure the achievement of target of the AMRIT Scheme.**

**(iv) Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)**

4.2.20 Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) is being implemented by Bureau of Pharma PSUs of India (BPPI), under Department of Pharmaceuticals, for making quality medicines available at affordable prices for all, particularly the poor and disadvantaged, through exclusive outlets “Pradhan Mantri Bhartiya Janaushadhi”, so as to reduce out of pocket expenses in healthcare. Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) was launched with an objective of making quality generic medicines available at affordable prices to all and to have at least one Jan Aushadhi Store in each district of the country. Accordingly, under this scheme, dedicated outlets known as Janaushadhi Kendras are opened to provide generic medicines. Based on the recommendation of Committee of Secretaries set up by the Prime Minister to deliberate on health-related issues it was decided to expand the “Jan Aushadhi Kendra”. A total of 1616 drugs (including 50 anticancer/oncology medicines) and 250 surgicals and consumables are currently included in the product basket of Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP). More than 8700 Jan Aushadhi Kendras have been set up under the scheme, however, the target has been set up for opening 9300 Jan Aushadhi Kendras.

4.2.21 During the Committee's meeting held on 8<sup>th</sup> July, 2022, the Chief Executive Officer PMBI apprised the Committee about the PMBJP Scheme as under:-

*"The PMBJP scheme procures the products from various vendors who are having WHO GMP facilities, which is a standard for production of these medicines through e-tender portal of the Government of India. So, the process is entirely transparent...SAP-based inventory management and forecasting system is in place...the entire warehousing and logistic mechanism. So, IT-enabled SAP-based end-to-end supply chain system is there...warehouses are located at four locations, Gurugram in North, Chennai in South, Guwahati and Surat. So, all the four corners of the country are catered through these warehouses. In addition to the supply through the central warehouses and regional warehouses, a network of 39 distributors in different States, average one to two in bigger States. On their demand, also supply to these jan aushadhi kendras or the retail shops. There is a computerized system. These shops place direct order either to the distributor or to the warehouse. There is also a mobile app jan aushadhi sugam for public information and for facilitation. So, people can search the location of the nearby stores in their vicinity and also the medicines and they can compare the names and prices of the medicines through this app."*

4.2.22 The Committee has been informed by the Department of Pharmaceuticals that the Scheme is operated by government agencies as well as by private entrepreneurs having following key features:-

- (a) The incentive provided to the Kendra owners has been enhanced from existing Rs. 2.50 lakh to up to Rs. 5.00 lakh to be given @ 15% of monthly purchases made, subject to a ceiling of Rs. 15,000/- per month.
- (b) One-time incentives of Rs. 2.00 lakh is to be provided to the PMBJP Kendras opened in North-Eastern States, Himalayan areas, Island territories and backward areas mentioned as aspirational district by NITI Aayog or opened by women entrepreneur, Divyang, SC & ST in the form of furniture & fixtures.
- (c) Prices of the Jan Aushadhi medicines are 50%-90% less than that of branded medicine's prices available in the open market.
- (d) Medicines procured only from World Health Organization – Good Manufacturing Practices (WHO-GMP) certified suppliers for ensuring the quality of the products.
- (e) Each batch of drug is tested at laboratories accredited by 'National Accreditation Board for Testing and Calibration Laboratories' (NABL) for ensuring best quality.

**4.2.23 The Committee finds in the PMBJP Scheme that there is a word called 'Divyang' which is a sanskrit word. The Ministry of Social Welfare has urged upon to replace the word 'Divyang' with the word 'Physically Challenged or Differently Abled Person' as the word 'Divyang' is not understood to many. The Ministry of Social Welfare has sent a directive to the Ministry of Railways to replace the word 'Divyang' in IRCTC forms with english words. The Committee, therefore, recommends the Department of Pharmaceuticals to replace the word 'Divyang' with the word 'Physically Challenged or Differently Abled Person'.**

4.2.24 As regards the quality of cancer drugs being delivered at the Jan Aushdi Kendras, the Secretary, the Department of Pharmaceuticals categorically stated that the quality of drugs falls squarely in allocation of business for Department of Health & Family Welfare where CDSCO headed by the Drug Controller General of India are seized of the subject of ensuring the quality of drugs, and the department control both approval for manufacturing as well as for market access. The Department of Pharmaceuticals makes attempt to maintain high quality of the drugs that are made available through the Jan Aushdi Kendras. The Secretary, the Department of Pharmaceuticals further emphasized on the issue as under:-

*"We have a written document...It is an assurance provided in writing that the percentage of medicines of poor quality, we call it Non Standard Quality, in open market as per the CDSCO, who is the responsible authority for quality, it is 3.04 per cent, while in the PMBI shops, wherever they have been inspected or tested, it is 0.33 per cent. It means 10 times better quality has been established in the products sold in the PMBI shops despite the fact that they are lower in price. Although they are generic, although they are lesser priced, they are 10 times better in terms of quality assurance."*

4.2.25 A medicine under PMBJP is priced on the principle of a maximum of 50% of the average price of top three branded medicines. Therefore, the price of Jan Aushadhi Medicines is cheaper at least by 50% and in some cases, by 80% to 90% of the market price of branded medicines. In the financial year 2020-21, PMBJP achieved sales of Rs. 665.83 crores (at MRP), which has led to estimated savings of approximately Rs. 4000 crores of the common citizens of the country.

**4.2.26 The Committee appreciates the efforts of Pharmaceutical and Medical Devices Bureau of India (PMBI) in implementing Pradhan Mantri Jan Aushadhi Pariyojana (PM-BJP) that intends to provide quality generic medicines at affordable costs through 8700 Jan Aushadhi Kendras. The Committee is of the view that PMBI should not only intend to operate Jan Aushadhi Kendras in all the 739 districts of the Country but incorporate into its strategy to open the Jan Aushadhi Kendras at the Block Level to ensure the accessibility of affordable and accessibility of cancer medicines to the patient at the door step. The Committee hopes that the Department of Pharmaceuticals would achieve the target of opening of 9300 Jan Aushadhi Kendras during current financial year. The Committee further recommends the Government to ensure that prescribed quality anti-cancer formulation drugs are available at the Jan Aushadhi Kendras all the time or made available within reasonable time.**

**4.2.27 The Committee is of the view that under cooperative federalism institution arrangement of cancer treatment should be well knitted & integrated with coordinated structure and functional equilibrium were the vision of cancer treatment at affordable cost flow from primary health centre at the block level to the tertiary level of cancer care i.e. a network of basic to complex form/procedure of cancer treatment.**

4.2.28 In response to the Committee's query regarding the measures that have been taken by the Department of Pharmaceuticals to strengthen the supply-chain so as to ensure that the availability of anti- cancer medicines in public hospitals and Jan Aushadhi Kendras, the Department stated that the logistics system of PMBJP is being strengthened. At present four modern warehouses at Gurugram, Guwahati, Chennai and Surat for storage and distribution of drugs are functional with storage area of approx. 2,15,000 Sq. Fts. PMBI is doing direct supply to stores from our warehouses to ensure sufficient availability of medicines at all the stores. Besides this, PMBI has a strong distributor network of 39 distributors in all corners of the nation to support the supply of medicines to remote and rural areas.

4.2.29 In order to ensure availability of medicines, an Information Technology (IT) enabled End-to-End supply chain system with Point-of-Sale (POS) application for value added services has been implemented by PMBI to monitor end to end supply chain management system. All kendras have a choice to place orders from any of the distributor or from Gurgaon Central Warehouse or Chennai/Guwahati/Surat warehouse also. These are backed by SAP based inventory management system. Thus, a competitive system has been created where stores have an option to procure from distributor or PMBI directly.

**4.2.30 The Committee appreciates the supply chain arrangement made by the Department of Pharmaceuticals, however, it is expected that the structural arrangement of supply chain management must have adequate functional operational mechanism to have the robust management for ensuring availability of medicine in all the PM Jan Aushdi Kendras.**

### **Rashtriya Arogya Nidhi (RAN)**

4.3 Treatment of cancer is either free or subsidized in the Government Institutions. Further, financial assistance is provided to poor patients for their cancer treatment under the Health Minister's Cancer Patient Fund component of the Umbrella scheme of the Rashtriya Arogya

Nidhi (RAN). Under the Umbrella Scheme of Rashtriya Arogya Nidhi one-time financial assistance upto Rs. 15 lakh is provided to patients belonging to poor patients living below threshold poverty lines and suffering from major identified life-threatening diseases for medical treatment at Government hospitals. The Scheme has three components, namely (i) Rashtriya Arogya Nidhi (RAN)- to provide financial assistance to patients suffering from life threatening diseases other than Cancer, (ii) Health Minister's Cancer Patients Fund (HMCPF) - to provide financial assistance to patients suffering from Cancer; and (iii) Scheme for financial assistance for patients suffering from specified rare diseases. As per the information given in Annual Report 2021-22 of the Department of Health & Family Welfare, an amount to the tune of Rs. 4.8905 Cr. were released under Health Minister's Cancer patient fund for facilitating 54 patients.

4.3.1 The Rashtriya Arogya Nidhi (RAN) focuses on the following issues:-

- (i) One time grant; availed multiple times for different ailments; no part payments.
- (ii) Treatment at Government Super Speciality Hospitals.
- (iii) Network-43 hospitals, Cancer Care Centres and other Government Hospitals
- (iv) Defined life saving procedures and treatment for rare diseases
- (v) Coverage upto Rs. 15 Lakhs
- (vi) Post treatment payment to hospitals
- (vii) IT based transparent process
- (viii) Poor patients - PM-JAY SECC & NFSA Antyodaya

### **Cancer Care Pathway Limits**

4.4 Various key barriers in the current cancer care pathway limits the access to affordable and quality cancer care in India. The cancer patient pathway points to multiple challenges for patients at each stage of their journey, tackling these issues requires complex preventive, diagnostic, therapeutic and supportive care services. The following cancer patients pathways highlights the building blocks to establish a comprehensive cancer care ecosystem that delivers affordable and quality cancer services to citizens of the Country.

<b>Barriers across Cancer care pathway</b>	<b>Awareness and Prevention</b>	<b>Screening and Diagnosis</b>	<b>Treatment</b>	<b>Monitoring and Surveillance</b>
<b>Patient</b>	Limited awareness and poor health seeking behaviour	Inadequate access to basic health facilities especially in remote areas	Low Patient affordability and Lack of seamless experience	No longitudinal tracking of patients leading to poor treated outcomes.
<b>Health System</b>	Human Resource Capacity & Capability Issue and Traditional less effective methods	Ill-equipped labs and facilities especially in the rural areas.	Siloed operations having manual process, therefore, time consuming; and Constraints of Oncologist capacity and capability.	Limited focus on measuring outcomes and patient satisfaction; and lack of structured and interoperable data.

<b>Payer/Policy</b>	Lack of Policy Level Intervention of National Scale	Lack of coverage for diagnostic services	Low overall healthcare budget; and low acceptance of value-based pricing for reimbursement.	No National/State Cancer Registry; and System incentivized by volume & fee for service
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**4.4.1 The Committee understands that Cancer care delivery in developing nations has always posed big questions around accessibility and affordability for most of its population. Access to the right doctors, facilities, treatment, and medication in a timely manner is limited to a few metro cities and thus, large parts of the country lack access to quality healthcare services. The Committee, therefore, recommends the Government for making policy for decentralization of cancer care facilities and treatment from metro cities to class I and II cities.**

**4.4.2 The Committee takes into account that efficient delivery of cancer care is further challenged by regional disparity, marked socio-economic diversity, gaps in knowledge, health seeking behavior of the public combined with resource and infrastructure constraints. Approximately 80% of the cancer patients seek medical attention in advanced stages of disease that contributes to India’s very high mortality-incidence ratio of 0.68 which is substantially higher than that of high-income countries (HICs) (0.38). The Committee, therefore, recommends the Government to take these facts into consideration while chalking out strategy to combat the menace of higher incidence of cancer.**

**4.4.3 The Committee finds that the public tertiary level hospitals available across India, that provide cancer treatment, are less than 50 in comparison to the private facilities which are more than 200 in number across India. That clearly states that the infrastructure for cancer treatment in India has been tapped more deeply by private facilities than the Government facilities. Therefore, with incremental annual prevalence of approximately 14 lakhs cancer diseases in India, the burden of cancer patients on 250 health facilities has led to an unmet need or demand-supply/service delivery gap for cancer care in India. The Committee is of the considered view that there is an urgent need to expand the network of Government funded cancer treatment infrastructure to take care of increasing incidence of registered cancer patient.**

**Cost of Cancer Treatment**

4.5 Pertaining to the Committee's query on the high cost of cancer treatment, the Secretary, Department of Pharmaceuticals mention that the bill of treatment not only covers the price of the drugs but also the invoices for treatment from the hospital, doctor's charges & consultation fee, nursing charge, test and lab charges, maintenance charges, bed plan charges and cleaning charges etc. which unfortunately does not fall within the mandate of NPPA. There are clinical establishment rules or Act which have been administered by various States. The mandate of the NPPA regulation on medicines so as to reduce the cost of medicine. The Secretary further submitted that NPPA impose ceiling price or TMR thus asking the manufacturers of the retailers to bear that cost so that it does not become unaffordable for the public.

4.5.1 The Committee has been apprised that almost 70% of cancer patients receives radiotherapy treatment. Radiotherapy equipment are costly. As per World Health Organization (WHO) norms, 1 Tele-radiotherapy machine is required per 10 lakh of population. As such, India requires about 1,300 tele-radiotherapy machines. The country at present have approximately 700 machines. Therefore, there is long waiting period for treatment which results in poor survival.

**4.5.2 The Committee understands that the cost of cancer treatment is not only the price of the medicine but the cost of healthcare for any patient in the country includes a variety of charges viz. doctor consultation and nursing fee, room charge, pathological and maintenance charges thereby increasing the overall cost of the treatment. The Committee finds that Government is providing subsidized food, heavily subsidized power, however, inaccessible and increasing cost of cancer treatment is a matter of concern for the Committee, as not only the patient but the whole family undergoes tremendous psychological and economic pressure in bearing the cost of the treatment and sailing through troubled phase of life. The Committee, therefore, considers it pertinent, on the part of the Government, to take suitable measures not only for regulation of medicines having focus on reducing the cost of the medicine but to provide subsidized healthcare by regulating the cost of diagnostic and treatment kits and service charges for various components of healthcare rendered not only in Government Hospitals but also in the private hospitals.**

**4.5.3 The Committee takes into consideration the high cost of radio therapy resulting into unaffordable cancer treatment. The Committee is in agreement with the argument of Secretary, the Department of Pharmaceuticals that NPPA is mandated only to control drug charges through DPCO and not the service charge because radio therapy service has not been declared an essential commodity/service under the Essential Commodities Act-1955 or by NLEM. The Committee, therefore, recommends the Government to examine as to the types of services should be regulated in terms of price and therefore be made provision of the Essential Commodities Act-1955. The Committee hopes that the Ministry of Health & Family Welfare would take the matter on board for final decision.**

#### **Poor availability of radiation machines in the Government Hospitals**

4.6 The Committee was further informed that few Government-run Medical Colleges in Delhi do not have radiation machines but have Radiation Oncology Department. There are six Government-run medical colleges in Delhi and only two of these colleges have radiation machines which are functional to the best of their capacity. However, radiation oncology department is present in all the medical colleges. The radiation machines are present at AIIMS, Delhi, Safdarjung Hospital and Delhi Cancer Institute. Maulana Azad Medical College or LNJP associated Lady Hardinge Medical College do not have radiation machines but have Radiation Oncology Departments.

4.6.1 The Director, BCCI in his submission before the Committee also stated that BARC has developed and designed an indigenous technology called Bhabhatron Teletherapy Machine which is 50 per cent of the cost of imported machine. The machine has also been upgraded to MLC and now a linear accelerator is being introduced. Once it is successfully commissioned, the cost of the equipment will drop down significantly.

**4.6.2 The Committee notes that lack of adequate number of equipments in the hospital increases the waiting period for treatment. During the course of the examination of the subject, the Committee noted that the country imports radiotherapy machines from other countries and there is gross shortage of radiotherapy machines in the medical colleges. The Committee further observes that the cost of radiotherapy is very high in private sector largely because of the fact that radio therapy machines are not manufactured in our country. The Committee accordingly recommends the Ministry to work on a mechanism under which either the machines are assembled in the country or are indigenously manufactured in the country. The Committee further strongly recommends the Ministry to ensure that radiotherapy machines are made available in the Hospitals/Medical Colleges that have Radiation Oncology Department.**

**4.6.3 The Committee notes that the Bhabhatron-II TAW Cobalt-60 Teletherapy machine is fully indigenous unit and is highly cost-effective compared to imported versions of Cobalt-60 teletherapy units. The Committee accordingly recommends the Government to encourage such indigenous manufacturing and promote collaborations between apex research bodies and Ministries/Departments in the country.**

#### **Case Study: Average travel time to access Radiotherapy Facilities**

**4.7** Varian Medical Systems in its memoranda submitted to the Committee has stated that though the Government is working towards improving the infrastructure for Cancer Diagnosis by focusing on setting up AIIMS like institutions and upgradation of government medical colleges and institutions, however, it must be recognized that despite the efforts, only a fraction of actual cases are being attended to. Tertiary care institutes tend to be overburdened with more cases being diagnosed through government efforts for which infrastructure is required to be ramped up to ensure matching of demand and supply.

India remains short on infrastructure parameters:

- India has 0.9 medical oncologists (vs 33 in USA) per million population.
- 1.5 radiation oncologists (vs 20 in USA) per million population.
- India has 0.3 linear accelerators (against a world average of 1.8) per million population.

4.7.1 Furthermore, a large gap is found in radiotherapy infrastructure. In India, less than 20% of the patients receive radiation treatment on an average, due to lack of access and affordability concerns. Radiotherapy is one of the three pillars of cancer treatment, along with chemotherapy and surgery, and is a highly personalized, targeted, and cost-effective form of treatment. Thus, while the use of Radiotherapy services exists as an effective tool to treat cancer, it is not leveraged fully in India. This further result in patients having to travel long distances to access treatment, further adding to financial burden and large share dropping out of treatment.

4.7.2 Radiotherapy facilities are available only in 100 districts, people in districts without Radiotherapy facilities are forced to travel long distances to avail treatment. Resultant financial hardships force many patients to leave the treatment midway.

4.7.3 The image shows average travel time for people in Bihar where Radiotherapy facilities are centralised in Patna.



4.7.4 As continued efforts are made to match supply of services covering primary, secondary and tertiary care, special attention needs to be paid for upgrading radiotherapy infrastructure to:

- (a) Meet current demand by providing access to patients close to their homes.
- (b) Meet future demand as cases rise including for radiotherapy

**4.7.5 The Committee notes that improving the prevention and screening scenario in cancer care would only bear results if the diagnostic infrastructure is ramped up to ensure there is matching of demand and supply. The Committee recommends the Ministry to improve both technological and human resources in the healthcare institutions as trained manpower and technology resources are complementary to each other. Improving the diagnostic infrastructure in the medical colleges and hospitals would improve the access and thus patients would not have to travel long distances to access treatment facilities.**

### **Imported Cancer Drugs**

4.8 The Committee has been informed that some cancer medicines which are being imported from other countries are having very high price. Some injections cost about Rs. 2,00,000 to 5,00,000 in a private hospital. The Secretary, Department of Pharmaceuticals mentioned that NPPA's regulation applies to both the domestically manufactured drugs and the imported drugs.

4.8.1 During the Committee's study visit to Tata Memorial Hospital Mumbai on 28<sup>th</sup> April, 2022 the Committee has been apprised that Bhabha Atomic Research Centre (BARC) has developed products for affordable cancer diagnosis & treatment. Some of the products developed and launched by BARC with their applications and price at which products are offered *vis-à-vis* the imported price is tabulated below:

S.No.	Product Name	Form	Application	BARC Price (Rs.) + 18% GST	Import Price (Rs.)
1.	<sup>90</sup> Y-DOTA-TATE	Injection	Neuroendocrine cancer therapy	79,603/-	2,00,000/-
2.	<sup>90</sup> Y-glass microsphere (BhabhaSphere)	Injection	Treatment of liver cancer	50000/- (Tentative)	5,80,000/- (TMH) ~8,00,000/- (Private hospitals)
3.	<sup>177</sup> Lu-PSMA-617	Injection	Prostate cancer therapy	37,000/-	~2,00,000/-
4.	<sup>177</sup> Lu-DOTA-TATE	Injection	Neuroendocrine cancer therapy	43,650/-	~1,50,000
5.	<sup>131</sup> I-Lipiodol	Injection	Liver Cancer therapy	35,700/-	~2,00,000/-
6.	<sup>68</sup> Ga-DOTA-TATE	Injection	Neuroendocrine tumor imaging	6,500/-	~28,000/-
7.	<sup>68</sup> Ga-PSMA-11	Injection	Prostate cancer imaging	7,940/-	~21,000/-

4.8.2 As can be seen from the above table, the indigenously developed products by BARC is made available at fraction of the imported cost.

**4.8.3 The Committee recommends the Government to provide basic infrastructure to the manufacturers of drugs for manufacturing cancer drugs that are presently being imported at high price, in the country itself under Make-in-India Programme so that the prices can be reduced and made affordable. The Committee also recommends the Government to make an effort to support or incentivize the industry to go for R&D and start manufacturing high-end drugs in our country so that the country can become *atmanirbhar* or self-reliant. The Committee takes into account that the Department of Pharmaceuticals is supporting the pharmaceutical industry under the PLI Scheme. Under the said scheme the Department of Pharmaceutical gives an incentive of 5% to 10% for various kinds of new drugs to incentivize generic manufacturers to move towards new types of drugs. The Committee, accordingly recommends the Government to encourage the Pharmaceutical industry to manufacture costly cancer drugs, which are being imported right now, at the cheaper price on the line of Bhabha Atomic Research Centre (BARC).**

## **Pradhan Mantri Jan Arogya Yojana (PMJAY)**

4.9 The Pradhan Mantri Jan Arogya Yojana (PMJAY) aims at providing health insurance cover of Rs. 5 lakhs per family per year for secondary and tertiary care hospitalization to over 10.74 crores poor and vulnerable families (approximately 50 crore beneficiaries).

4.9.1 The households included are based on the deprivation and occupational criteria of Socio-Economic Caste Census 2011 (SECC 2011) for rural and urban areas respectively. Since the inception of the scheme, treatment for cancer diseases is included in the benefit packages of PM-JAY. All modes of treatment for cancer (Medical Oncology, Surgical Oncology and Radiation Oncology) are covered under the scheme.

4.9.2 The Committee sought to know the measures that can be taken to rationalize treatment packages and tariffs under the AB-PMJAY and the changes required in the Ayushman Bharat Scheme so that the scheme coverage can be broadened and more beneficiaries are included irrespective of the SECC criteria. The Committee also desired to know various types of cancer related procedures that can be included under Ayushman Bharat. Responding to the Committee's query the Department of Atomic Energy furnished a written submission as under:-

*"The NCG has MoU with the National Health Authority and worked closely with the NHA in rationalizing the packages and tariffs under the AB-PMJAY since HBP 2 (Health benefits Packages 2). This has continued into HBP 2022, and all packages in cancer so far under AB-PMJAY have been worked upon by experts within the NCG. This process is an ongoing one, with new packages being added as data to support them becomes more mature. The government is contemplating including the "missing middle" also in a government-subsidized health insurance scheme which will further increase the scope of the AB-PMJAY."*

**4.9.3 The Committee observes that despite the launch of AB-PMJAY to increase universal health coverage, healthcare in India is largely financed through out-of-pocket payments and remains unaffordable for a large part of the population. Though initiatives like Ayushman Bharat and National Digital health Blueprint have created a foundation for health integration, the delivery of cancer care in the country remains largely fragmented leading to patient leakages within the health system and resulting in poor treatment outcomes. The Committee, however, hopes that AB-PMJAY and National Digital health Blueprint would go a long way in delivery of cancer care system.**

**4.9.4 The Committee has been apprised that one among the five cancer insurance claims is by patient belonging to 36 to 45 years of age, thereby resulting into the loss or disruption of household income. As per the National Sample Survey Healthcare even average out of pocket spending on cancer care is too high. The out of pocket spending for cancer care in private facilities is about three times that of public facilities. About 40% of cancer hospitalization cases are financed mainly through borrowings, sale of assets and contributions from friends and relatives. Considering such a glaring gap in affordability when it comes to quality cancer care, the Committee feels that there is a strong need to make cancer care affordable through suitable interventions from both Government and private sectors.**

**4.9.5** The Committee is of the view that adequate measures can be taken for convergence between state and central health schemes with similar beneficiary bases. The Committee observes that some State Governments have successfully implemented their own state-specific health insurance scheme on top of AB-PMJAY considering their local socio demographics and disease burden. In the opinion of the Committee state specific insurance has been highly beneficial to the community at large. The Committee understands that having both the depth and coverage the AB-PMJAY can increase more beneficiaries and better treatments. On similar lines, the governments should take steps towards the convergence of health schemes thus providing more comprehensive coverage in case of catastrophic expenses brought upon by cancer incidence in a household.

**4.9.6** The Committee finds that besides the devastating effect of cancer in terms of morbidity, the cost involved in managing the disease puts unbearable economic burdens on individuals, their families and on the nation. The high cost of cancer healthcare often leads to a substantial financial burden on the patient and their family. One third of household with individuals with cancer are estimated to spend more than half of their per-capita annual household expenditure on hospitalizations.

**4.9.7** The Committee takes into account all the measures undertaken by the Government for making cancer much more affordable without compromising on the quality of treatment given. Most curative treatment is affordable especially when patients get treatment under the AB-PMJAY scheme of the government. The upgradation of Government Hospitals with oncology departments and 25% reservation on cancer services provided in private hospitals for patients treated on government schemes will offer affordable cancer care to patients. Increasing funding for cancer research that evaluates low-cost technology, repurposed drugs and indigenization of equipment will reduce costs in the long run. The Committee understands that linking adherence to the NCG resource stratified guidelines to reimbursement under Government schemes will bring down costs. The NCG has also conducted group negotiations for cancer drugs which has resulted in procuring high quality drugs at 20 to 90% discount from MRP, which should be passed on to patients.

**4.9.8** The Committee takes into consideration that since the cost of newer therapies are expensive, therefore, the Government should leave no stone unturned in making the cancer treatment affordable. In this regard, the Committee recommends that a concerted effort must be continuously made to bring clinician scientists, industry & academicians, biotechnologists, cell biologists, bioinformatics, immunologists to develop Chimeric Antigen Receptor (CART-cell) therapy in the country. The Committee endorses the views of the Department of Biotechnology for the implementation of two projects, namely:

- (i) Development of genetically engineered ‘off-the-shelf’ and inducible CAR T-cell for cancer therapeutics;**
- (ii) Research on glioblastoma stem cell-targeted T-cell immunotherapy using non-genetically engineered mesenchymal stromal cells.**

**4.9.9** Replying to the Committee's query as regards the high charge for treatment of cancer in the private hospital and whether the Government should establish a network of Government hospital across the country for providing affordable cancer treatment, the Department of

Biotechnology suggested that in order to develop affordable cancer treatment, the Department of Biotechnology along with its PSU, BIRAC is promoting and supporting research and development projects for affordable cancer treatment.

4.9.10 The Biotechnology Industry Research Assistance Council (BIRAC), a Public Sector Enterprise, of Department of Biotechnology (DBT), Government of India has established a Clinical Trial Network program by supporting 17 hospital sites including a public-private hospital collaboration and disease registries of cancer on one platform for all centers. BIRAC is supporting projects for development of cancer treatment through the Public Private Partnership Schemes. Some of its projects include:

- (i) Preclinical Efficacy and IND-enabling Studies of a Novel Oral ENPP1 Inhibitor for Cancer Immunotherapy;
- (ii) Novel ULK1 inhibitors for treatment of resistant cancer patients for improved clinical outcome;
- (iii) Chimeric Antigen Receptor CAR -T cells technology for cancer treatment: Development of a pre-clinical grade manufacturing process as per Industry standards;
- (iv) Development of Bevacizumab for the treatment of colorectal cancer
- (v) Adaptation and validation of dendritic cells-based therapy for treatment of cancers

4.9.11 The Department of Biotechnology emphasized that for prevention and diagnosis of cancer, the Department along with its Public Sector Unit (PSU) BIRAC, has implemented projects that *inter-alia* included the following:

- (i) An Affordable, Point-of-sample collection, Cervical Cancer detection system
- (ii) Minimally invasive nano enabled targeted technology for Sentinel Lymph Node SLN detection
- (iii) Imaging device for monitoring breast tissue changes

**4.9.12 The Committee finds that the charge for cancer treatment is high in the Private Hospitals, therefore, more Government Hospitals should be established across the country for providing affordable cancer treatment. The Committee endorses the views of the Department of Atomic Energy that existing Government hospitals should be upgraded to create oncology departments; these departments should also have “private patients” who pay for their care, and partially subsidize the “free’ patients who are not charged. Similarly, 25% reservation on cancer services provided in private hospitals should be earmarked for patients treated on government schemes. The measures so undertaken would ensure not only affordability of care but also ensure that the doctors in both Government and private hospitals deliver healthcare services and treatment of patients from all strata of society.**

**4.9.13 The Committee takes into account that about forty percent of cancer hospitalization cases are financed by informal financial tools. A major part of treatment expenditure is availed from informal credit at high rates of interest. Due to high mortality rate in Cancer, the net outcome for the household happens to be an insurmountable debt when the earning member of the family demises. The Committee, therefore, considers that easily accessible credit line through formal**

channels is highly needed to fill the gap, however, at present there are few such medical/healthcare loans options available in the Indian market primarily offered by Non-Banking Financial Companies (NBFCs) charging interest rate as high as 13% to 15% and with limited loan amount. That again raises a concern of affordability, hence, it is imperative to encourage major nationalized banks to create such product which is affordable for the public to use it as an emergency fund. The Committee, therefore, recommends the Government to encourage Nationalised and Corporate Banks for creation of more credit tools to meet catastrophic healthcare needs in critical cancer care segments.

### **Cancer Treatment Protocol**

4.10 The Departments of Health research (DHR), ICMR has developed DHR-ICMR Advanced Molecular Oncology Diagnostic Services (DIAMoNDS) on a Hub and Spoke model. The objective is to provide free of cost pathological diagnosis of cancer to patients. In first phase, Breast and Lung cancer have been included at 4 major centres (AIIMS-New Delhi, TMH-Mumbai, CMC-Vellore, TMC-Kolkata) as hubs and another 7 centres in different parts of India as spokes. A total of 2700 patients have benefited till February 2022. Two more types of cancers viz. colon and uterus have been added for free testing in the list in March 2022.

### **Standard Treatment Guidelines**

4.11 Standard Treatment Guidelines for Oncology have been developed by expert groups for 20 different cancer sites brought out by Indian Council of Medical Research (ICMR) and work on 18 cancer sites is ongoing. ICMR-NCDIR formulated the "Framework for Telemedicine use in Management of Cancer, Diabetes, Cardiovascular Disease and Stroke in India". The framework covers the benefits of telemedicine in cancer care, scope of telemedicine consultations in oncology and clinical scenarios where telemedicine can be used for surgical /medical /radiation oncology/palliative care. ICMR has also developed Standard Operating Procedure for detection of neoplasms.

4.11.1 During the Committee's meeting held on 7<sup>th</sup> July, 2022, responding to the Committee's query on the measures that Government must take to create a cancer treatment protocol in the country and the changes required in the cancer policy of Government, the Department of Atomic Energy maintained that the National Cancer Grid (funded by the DAE) has developed national guidelines and protocols for treating cancer, which have been adopted by the National Health Authority for reimbursement under the AB-PMJAY scheme.

4.11.2 Addressing the issue of cancer treatment protocol in the country, the Department of Biotechnology mentioned that the National Cancer Grid has been actively involved in developing treatment protocols for common cancers. However, the rapid progress being made and with new drugs entering the market, it necessitates frequent revisit to the recommendations.

**4.11.3 The Committee is of the view a dual approach is required for planning a systematic National Cancer Plan. On the one hand the Government should make attempt to strengthen the existing centres to provide uniform standards of cancer care across the country and on the other hand, additional Government run cancer**

**centres should be established to fill up the gaps in access to care breaking geographic barriers. The Committee, in this regard, recommends the National Cancer Grid, a large network of cancer centres, research institutions, patient groups and professional societies, to continue to yoke the responsibility of carrying out the first approach.**

**4.11.4 The Committee appreciates the role and responsibility of the National Cancer Grid, an initiative of the Department of Atomic Energy, in taking care of about 60% of all of India's cancer burden and the Committee hopes that NCG, incorporating all the experience and vision of all stakeholders of cancer care in India will play pivotal role, unified and powerful voice in the fight against cancer.**

### **Scientific Advancement**

4.12 The Committee desires to know how the scientific advancements like Artificial Intelligence and Machine Learning *etc.* can be used for making cancer treatment affordable and accessible in the country, the Department of Atomic Energy submitted that TMC has already developed a web-based online solution “Navya” which uses AI for suggesting evidence-based treatment options for patients with cancer from any part of the country. This offers an expert opinion to patients without the need for them to travel long distances to get access to an expert opinion. In addition, TMC is involved in several research studies evaluating AI and ML in radiology and pathology.

4.12.1 The Committee has been informed by the Department of Atomic Energy that knowledge sharing and technology transfer and collaboration with International Cancer Research Organisations has helped the country in cancer care and treatment. Several international agencies support cancer research and training in India. The International Agency for Research on Cancer supports the TMC South East Asian hub for cancer registries, which is an important resource to evaluate the burden of cancer in India. The International Atomic Energy Agency supports training as well as research studies mainly focusing on radiation technologies. The National Cancer Institute funds cancer research and supports training opportunities in cancer research. Funding for cancer research, especially clinical and epidemiological cancer research has to be increased. The research should focus on low-cost effective technologies, repurposed drugs and indigenization of equipment and technologies. In addition, training in research methods should be encouraged at undergraduate and postgraduate medical education level.

4.12.2 On the issue of knowledge sharing and technology transfer and collaboration with International Cancer Research Organisations that helps the country in cancer care and treatment, the Department of Biotechnology informed the Committee that in the International Cancer Genome Consortium (ICGC) with India as a founding member, knowledge sharing and technology transfer were central pillars to accelerate discoveries to help cancer diagnosis and treatment. Working with the leading cancer and genomics research organization in the 5 continents including the National Cancer Institute (NCI), USA, India gained in developing best international practices in tumor bio banking, patient consenting process, whole exome and genome analysis and its clinical correlation. Novel genomic signatures and immune profile were identified in tobacco chewing-associated oral cancers prevalent in India. These findings were validated to show how they influenced cancer spread to lymph nodes and patients' survival and possible response to drugs and chemoprevention. These genomics leads and cell lines made from Indian oral cancers are being used by Indian researchers to improve diagnosis and drug development.

4.12.3 The Department of Biotechnology in its written submission stated that Artificial Intelligence (AI) and Machine Learning (ML) are making an impact in imaging. Considering this immense importance of AI and in accordance to the NITI Aayog's strategy of AI for All, DBT is supporting projects on Artificial Intelligence Applications for Affordable and Accessible Healthcare - Big Data and Genomics. Under the program, Department is supporting a project on Imaging Bio Bank for Cancer at Tata Memorial Centre, Advanced Centre for Treatment, Research and Education in Cancer (TMC-ACTREC), Mumbai in collaboration with AIIMS, New Delhi, IIT, Bombay and Rajiv Gandhi Cancer Institute and Research Centre (RGCIRC), New Delhi. The project involves building a database of cancer-related radiology and pathology images derived from Indian patients, with focus on major cancers prevalent in India, along with the associated annotations and labels from clinical data, including but not restricted to, staging, diagnostic, treatment, response to therapy, genomic, outcomes, etc. This database is envisaged as a national resource which will be open to bonafide researchers from all parts of India. This comprehensive signature of cancer patients will act as a database to advance research in cancer, and is aimed at cancer diagnosis/prognosis and cancer care.

4.12.4 Regarding the use of scientific advancements like Artificial Intelligence and Machine Learning *etc.* which can be optimally utilized for making cancer treatment affordable and accessible in the country, the Department of Pharmaceuticals stated that the Department of Science & Technology (DST) is implementing a National Mission on Interdisciplinary Cyber Physical Systems (NM-ICPS). As part of the Mission implementation, 25 Technology Innovation Hubs (TIHs) have been established in reputed institutes across the country in advanced technologies. Some TIHs have initiated activities in the area of AI & ML, as applicable to cancer diagnosis. The details are as follows:

(i) IHub Drishti Foundation at IIT Jodhpur proposes to create a radiogenomics centre within the Hub, that will collect and curate Indian radiogenomics data. Radiogenomics centre will also perform basic and translational research to create artificial intelligence (AI) and computer vision driven diagnostics, prognostics and treatment for patients as part of precision medicine workflow. The platform will deliver radiogenomics services in collaboration with medical professionals. In a broader perspective, this will enable development of a unique multidisciplinary innovation ecosystem for AI and Computer vision driven precision medicine.

(ii) IHUB DivyaSampark, Technology Innovation Hub at IIT Roorkee is funding a start-up CogXR Labs Pvt. Ltd. that is developing screening tools for cancer using AI & ML with an aim to commence Healthcare 4.0 in India. It is a confluence of state-of-the-art cutting-edge technologies including, but not limited to, AI(Machine Learning and Deep Learning), Extended Reality (Virtual, Augmented, and Mixed), and Brain-Computer Interfaces.

(iii) AI4ICPS at IIT Kharagpur is working on developing National Knowledge Portal (NKP) as one of its top initiatives. Through this portal, in the future, the screening and diagnosis of cancer will be made accessible and affordable at large scale through pre-trained AI and ML models. This is also a portal for many curated course works. NKP could be leveraged to train the healthcare workers with AI models for better screening of cancer as part of assistive technologies for cancer diagnosis and care.

4.12.5 Further, under the Department of Science and Technology, Sree Chitra Tirunal

Institute for Medical Sciences and Technology (SCTIMST), an Institution of National Importance situated in Trivandrum, the capital city of Kerala, plays a unique role in development of bio-medical technology for patient care and interventions in the society through the public health wing blending the services with state-of-the-art clinical services in the fields of cardiac and neuro sciences. The hospital has 253 beds and serves as tertiary referral centre for cardiovascular, thoracic and neurologic diseases. With a number of highly qualified personnel the hospital provides state-of-the art care for thousands of patients each year. The hospital caters to more than one and a half lakh outpatients and a little over 10,000 inpatients each year.

**4.12.6 The Committee understands that the scientific advancement and technological development has a direct co-relation with affordability of cancer treatment because affordable cancer treatment requires a multi-modality sort of arrangement involving modern technology like radiation therapy & linear accelerator, radio therapy technique, machines, manpower, surgical oncology, nuclear medicine, medical oncology, preventive oncology and palliative care. The Committee has been given to understand that the Sanjay Singh University has worked on micro-RNA as biomarkers for early detection of cancer, therefore, such initiative can be undertaken in the Country for the development of biomarkers with clinical trials and development of new tools for cancer screening and early detection of cancer.**

**4.12.7 The Committee recommends the Government to procure and install the latest tools, techniques and equipments such as LINAC machine or PET scan in Government hospitals for cancer treatment at affordable cost because cancer treatment is not possible without PET scan machine as the same is one of the basic investigation needed for cancer treatment especially to diagnose the metastatic cases.**

**4.12.8 The Committee takes into consideration that the various departments in SCTIMST provide comprehensive surgical and interventional treatment as part of oncology related services. The Committee believes that the Patients especially from the economically weaker section of the society from all states of country would avail the benefits of the services of SCTIMST for neuro-oncology related ailments.**

#### **Patient Assistance Program (PAP)**

**4.13 The Committee further recommends the Government to encourage effective Patient Assistance Program (PAP) to enhance affordability of cancer treatment. Patient Assistance Programs (PAPs) make newer innovative therapies and treatments affordable for patients in India. The Committee feels that since the majority of patients end up paying for their treatments from their pocket, therefore, such PAPs could be of immense financial assistance. The Committee has been given to understand that the NPPA implements TMR for free supply of oncology drugs under Patient Assistance Program (PAP) and government supply at a pre-determined lower price. PAP is usually designed and sponsored by pharmaceutical companies to offer free units of the medicine against a unit purchased for the class of patients who are non-reimbursed or do not have sufficient insurance coverage which results in improved patient access and compliance with treatments. The Committee, therefore, recommends the Government to explore rational modalities for effective Trade Margin Rationalization (TMR) mechanism that can facilitate PAP programs for**

cancerpatients.

#### **Tariffs and Taxes on Cancer medicines**

**4.14** The Committee observes high Tariffs and Taxes on Cancer medicines as a matter of concern. As compared to other Asian countries in similar stages of development, import duties in India are very high although the basic import duties for pharmaceutical products average about 10 percent but as a result of the integrated GST (5 – 12%) imposed on imports, the effective import duty often *exceed 20 percent*. Furthermore, excessive duties on the reagents and equipment imported for use in research, development and manufacturing of biotech products make the cost of manufacturing cancer drugs too high. While certain essential and life-saving medicines may be granted exemptions from some of the taxes, the eligibility criteria are vague and subject to constant revision. The Committee, therefore, recommends that drugs and vaccines used in the prevention and treatment of cancer should carry minimum GST and should be exempted from customs duties. Such measures will bring down prices significantly and the benefit would be passed onto the patients directly.

#### **Public Procurement Order (PPO)**

**4.15** The Committee has been apprised that under the Public Procurement Order (PPO) of the government non-local suppliers are not eligible to bid in government procurement, except for some high value orders. Due to manufacturing complexities around patented, specialty the proprietary drugs are manufactured in select locations only and indigenization of these medicines in a short time span is impractical and will severely impact availability of these critical drugs. The Committee has been given to understand such ineligibility on the part of non-local suppliers is creating a major access barrier for a lot of patented, specialty and proprietary drugs to be reaching out to the patients in need. The Committee, therefore, recommends the Government to consider for allowing a PPO exemption for non-local suppliers in case of patented, specialty and proprietary drugs not produced in India.

#### **Indian Council of Cancer Research**

**4.16** The Committee is in agreement with the suggestion of Regional Institute of Medical Sciences (RIMS), Imphal Manipur for establishment of Indian Council of Cancer Research/State Cancer Epidemiology Centres to undertake & promote Cancer Research in India, contextual and relevant to the needs of the Country. The Committee is of the view that the proposed Indian Council of Cancer Research would create suitable research environment and provide appropriate infrastructural support. Besides that, the said council would also formulate framework for periodic training in research methods and good clinical practices for investigators.

#### **Enhancing Affordability of cancer treatment**

**4.17** The Committee recommends the Government to undertake the following strategic course of action for enhancing affordability of cancer treatment

- i. Strengthening of every District hospital with Oncology Wing (Surgery, chemotherapy & palliative care)**
- ii. Upgradation of the existing RCC to Cancer hospital**

- iii. **More awareness programme on utilization of central financial assistance to public & doctors for cancer treatment**
- iv. **Opening of cancer patient accommodation and transportation centres in every district under Govt.support or NGOs.**
- v. **Increased awareness among public and health workers about certified generic anti cancer drugs**
- vi. **Increased availability of certified generic anti cancer drugs in the market.**

#### **Prime Minister's views on cancer care management**

**4.18 Inaugurating the Homi Bhabha Cancer Hospital and Research Centre in Mohali, on 24<sup>th</sup> August, 2022, the Prime Minister envisaged that a good healthcare system doesn't just mean building four walls, but to prioritize holistic health care in health policy formulation. In this regard, the Committee endorses the Prime Minister's views on provision of health facilities in the country by working together on following six fronts:-**

- (i) **promotion of preventive health care**
- (ii) **Opening small and modern hospitals in villages**
- (iii) **Opening medical colleges and big medical research institutes in cities**
- (iv) **Increasing the number of doctors paramedical staff across the country**
- (v) **Providing cheap medicines and cheap equipments to patients**
- (vi) **Reducing the difficulties faced by patients with the help of technology.**

**4.19 The Committee is of the considered view that the Central Government as well as the State Governments should work in tandem to improve the health infrastructure for treatment of cancer and other diseases.**

## CHAPTER-V

### ACADEMIC TRAINING AND RESEARCH ACTIVITIES

5.1 India is called the ‘Pharmacy of the World’ and is the world leader in generic manufacturing, but, for India to move up the value chain in the pharmaceutical sector it is imperative that an ecosystem which fosters research and innovation is created. This will propel India to be the world leader in introducing innovative treatments. In the existing scenarios, the cancer diagnosis as well as treatment that have been adopted by patients and healthcare providers at large is conventional in nature. Hence, in order to develop and introduce innovative therapies in India, it is imperative to promote R&D and clinical trials.

5.1.1 The Ministry of Health and Family Welfare informed the Committee that the Ministry undertakes research in cancer treatment through ICMR under the Department of Health Research. Besides, the cancer prevention and research was being carried out by the institutions under the aegis of various Govt. Ministries/Departments such as the Dept. of Biotechnology (DBT), Atomic Energy Regulatory Board (AERB) and the Council of Scientific and Industrial Research (CSIR). The Ministry also informed that India was an active member of the International Agency for Research on Cancer (IARC) which is the specialised cancer arm of World Health Organisation (WHO). It also partners with EU, USA and other countries for pushing the frontiers of knowledge on cancer. Through the abovementioned multi-pronged strategies and interventions, it was envisaged that the cancer burden would be reduced in the years to come, as the Government of India was committed to save lives and eliminate suffering.

#### **Academic Training and Research Activities**

5.2 The Ministry of Health & Family Welfare submitted in the background note on the subject that research and training activities in the area of cancer were carried out by different organizations. The Ministry informed that Cancer Biology Research was one of the thrust areas of the Department of Biotechnology and was supported and promoted in an integrated way. This included resources to individual investigators and to institutions, providing leadership to national infrastructures to carry out basic, applied and clinical research and to develop new methods to prevent and treat disease and conduct research especially in challenging areas pertaining to different types of cancer; Breast Cancer, Cervical Cancer, Lung Cancer, Prostate Cancer, Oral Cancer, Retinoblastoma, Multiple Myeloma, Head & Neck Cancer, Myeloid Leukemia, Chronic Myeloid Leukemia and Ovarian Cancer etc.

5.2.1 Training and research activities were supported with budgetary provision under the Biotechnology Research and Development scheme of the Department of Biotechnology. Additionally, DBT implemented a program entitled ‘Pilot Projects for Young Investigators’ to investigate new hypothesis for establishing proof-of-concept in cancer research under which 113 young investigators have been supported with a budget of Rs 26.52 crores.

5.2.2 DBT funded several projects under Basic, Diagnostic/Biomarkers, Nanotechnology & Therapeutics, Animal model systems for the development of chemotherapeutic agents, target identification, synthetic chemistry for target inhibition, genetics & epigenetics of nationally relevant cancers, cancer stem cells and its use in diagnosis & therapeutics. It funded three 5-year Centres of Excellence; six Units of Excellence and two Virtual National Cancer Institutes, one on Breast Cancer and other on Oral Cancer.

5.2.3 The Department also funded a Systems Medicine Cluster (SyMeC) project entitled, “Multi-dimensional Research to Enable Systems Medicine: Acceleration Using a Cluster Approach” at Kalyani, West Bengal with Cancer as an example addressing basic and clinical question in Oral and Cervical Cancer.

5.2.4 The Department of Biotechnology, Department of Atomic Energy & National Cancer Grid signed a MoU on 22nd May 2019 (DBT DAE NCG MoU) for supporting joint activities in the area of cancer research. Under the aegis of this MoU, a proposal received from Tata Memorial Hospital, Mumbai is under active consideration for financial support and implementation by DBT.

5.2.5 DBT-AIIMS/NCI-India Translational & Clinical Research Partnership Center: ADBT-AIIMS/NCI-India Translational & Clinical Research Partnership Center has been recommended for implementation by DBT at a total cost of ₹ 43 Cr for a period of five years with the objectives to establish a state-of-the-art Cancer Genomic Research Facility for Personalized Medicine, to establish Early Detection Research Network (EDRN) program with International partnership, to establish a quality enabled “Bio-bank” for “India centric cancers” enhancing exploration and validation of novel diagnostic or therapeutic modalities and to establish an advanced animal facility for gene-manipulated and immune compromised small animals for preclinical cancer research and technology validation needed for planning of clinical trial.

5.2.6 Virtual Network Centres (VNCs) in Cancer Immunology & Immunotherapy: Three new VNCs have been approved for implementation. (a) A Phase 2 Randomized Controlled Clinical Trial to Evaluate the Role of Metronomic Chemotherapy and Dendritic Cell Vaccine in Recurrent Hormone Receptor Negative Breast Cancer; (b) Development of Genetically Engineered 'Off-the-shelf' and Inducible CAR-T Cells for Cancer Therapeutics, and (c) Network Centre for Research on Glioblastoma Stem cell-targeted T-Cell Immunotherapy using Non-Genetically Engineered Mesenchymal Stromal Cells.

**5.2.7 The Committee notes the various initiatives of the Department of Biotechnology in the field of cancer research and appreciates the initiative of signing the MoU on 22nd May 2019 between the Department of Biotechnology, Department of Atomic Energy & National Cancer Grid (DBT DAE NCG MoU) for supporting joint activities in the area of cancer research. The Committee acknowledges that the DAE has been spearheading in prevention, diagnosis and treatment of cancer in the country for more than five decades and the NCG which has come into existence recently to look after all the aspects of cancer throughout the country, hence the Committee hopes that the MoU will go a long way in revolutionizing the research in cancer with a greater budgetary support from the Department of Biotechnology.**

### **Council of Scientific and Industrial Research (CSIR)**

5.3 Council of Scientific & Industrial Research (CSIR) through its constituent laboratories namely, CSIR-Central Drug Research Institute (CSIR-CDRI), CSIR-Centre for Cellular and Molecular Biology (CSIR-CCMB), CSIR-Indian Institute of Chemical Biology (CSIR-IICB), CSIR-Indian Institute of Integrative Medicine (CSIR-IIIM) etc. has been pursuing R&D activities in the area of cancer. In doing so, CSIR efforts are focused on understanding the disease biology; disease diagnostics; drug discovery and development; studying the environmental & genetic causes of specific cancers in India and creating innovative platforms for enhancing the innovation in the domain.

5.3.1 The cancer research at CSIR-CDRI is primarily focused on prevention of woman's cancer particularly cervical and triple negative breast cancer (TNBC). CSIR-CDRI is also exploring on design and synthesis of new clinical entities (NCE) against clinically validated targets in TNBC. In addition to this, the team is also working on the development of novel biomarkers for breast and cervical cancer with an aim to diagnose the disease condition at early onset which in turn will be helpful in taking preventive measures well in advance and thereby reducing morbidity and case fatality. Simultaneously, the institute is involved in basic research in cancer in understanding the disease biology with the objective to discover new targets in breast cancer therapy. CSIR-CDRI is also conducting health awareness program regularly among the village population nearby Lucknow and also in student population visiting CSIR-CDRI. During last three years, health awareness outreach has covered more than 10,000 people including students at all levels.

5.3.2 CSIR-IIIM has been actively working in the anticancer drug discovery area, with the aim to discover new potent and effective preclinical candidates and take them to human clinical trials. CSIR-IIIM's extensive efforts in this area, has led to the discovery of IIIM-290, a new chemical entity which display favorable profile in all preclinical studies. The regulatory safety pharmacology (IND-enabling studies) of the lead is completed, and IND filed to DCGI in January 2020. The New Drugs Division of Central Drugs Standard Control Organization (CDSCO), Government of India granted the permission to CSIR-IIIM for conducting the clinical trial of this important drug candidate IIIM-290 in pancreatic cancer patients.

5.3.3 Researchers at CSIR-IGIB have found the mechanism by which controlling the levels of telomerase can help in reining in the growth of cancer cells and probably prevent cancer metastasis. A protein called telomerase when present in high amounts is known to promote cancer and spread of cancer (metastasis) in different organs. New mechanistic understanding enables researchers to design approaches that include small molecules and peptides to decrease telomerase in aggressive cancer cells. These anti-telomerase agents might have potential therapeutic value, which needs to be tested further.

5.3.4 Research at CSIR-IICB is focused to address different areas of Cancer mechanism, management and treatment. In the process, CSIR-IICB has been instrumental in garnering novel insights in terms of understanding the biology of the disease and also contributed significantly to paving ways for novel therapeutic approaches in Cancer treatment.

5.3.5 Research at CSIR-CCMB is focused to bring about a liquid biopsy system to detect breast cancer from a drop of blood.

5.3.6 CSIR has also been supporting drug research through its infrastructure and facilities as well as its creation of trained human resource to carry out drug research in the country. Recently CSIR has initiated two major R&D Programmes in the area of Cancer Research namely, (i) Pan CSIR Cancer Research Program aimed at delivering preclinical leads for breast and ovarian cancer (Nodal Lab: CSIR-CDRI; Participating Labs: CSIR-IICB, IGIB, IIIM, IICT, IMTECH, and NCL); and (ii) Indian Breast Cancer Genome Atlas Program to perform next-generation whole genome and transcriptome sequencing to characterize the landscape of genetic alterations underlying breast cancer in 300 Indian patients for comprehensive cancer genome analysis and validation of data created to identify driver alterations and differential gene expression signatures (Nodal Lab: CSIR-IGIB; Participating Labs: CSIR-IICB, CCMB, IMTECH).

## **Department Of Health Research (DHR):**

5.4 The Department of Health Research launched the 100% central government funded schemes in 2013-14 for establishment of Multidisciplinary Research Unit (MRUs) in State Govt. Medical Colleges and Model Rural Health Research Units (MRHRUs).

5.4.1 In the year 2013-14, Government launched an Infrastructure development Scheme for promotion of Health research across the country by establishing Multidisciplinary Research Units in State Government medical Units in the State Government Medical Colleges and Research Institutes. Since its introduction, the scheme has been very successful in realizing its objective of creating and strengthening research environment/infrastructure in the country. So far, 80 MRUs have been sanctioned by the Government. Of these 80 MRUs, 15 MRUs have 87 ongoing projects (list enclosed) on cancer and 6 have been completed. So far, there have been 12 publications on Cancer. The scheme provides for one-time non-recurring grant and annual recurring for undertaking Research including Cancer.

5.4.2 In the year 2013-14, Government also launched the Scheme for establishment of Model Rural Health Research Units (MRHRUs) with the objective to transfer technology in rural areas for improving the quality of health services and at the same time work as interface between new technology developers, health system operators and beneficiaries. These units work under the mentorship of one of the institutes of the Indian Council of Medical Research (ICMR), an autonomous council of Department of Health Research.

5.4.3 So far, 23 MRHRUs have been established in the different States and Union Territories. Presently, 5 projects are undergoing on Cancer in 4 MRHRUs namely Punjab, Himachal Pradesh, Maharashtra & Andhra Pradesh. The projects on cancer in MRHRUs include survival and quality of life among cancer patients, efficacy of using AV Magnivisualizer based screening programme for cervical cancer, efficacy of tissue autofluorescence imaging in the visualization of oral premalignant and malignant lesions, improving access for screening of common cancers among tribal women and multi-component intervention for reduction of risk factors of NCDs. The scheme provides for nonrecurring and recurring grant for undertaking Research including Cancer from the Central Government.

## **Indian Council of Medical Research:**

5.5 The Ministry apprised that Budget provision for cancer research activities of ICMR is approx 250 crore during the last five years. Various training courses in cancer education and research is being imparted by national and international organizations viz: WHO, African and SAARC/ASEAN countries, INCTR and IAEA.

5.5.1 The Ministry informed that the National Institute of Cancer Prevention and Research (NICPR) conducts online cancer screening training courses using ECHO (Extended Community Health Outcome) platform for Primary Health Centres (PHC) Medical Officers, Gynecologists, Dentists and Staff Nurses which is FREE of cost. The participants receive a completion certificate if they fulfil the eligibility criteria (attend a minimum of 10 out of 14 sessions, present a case and pass in the exit exam). The participants who successfully complete the online course are eligible for Hands-on training at NICPR, which is of 3 days' duration. Skill building is done during this training in which all the participants get to carry on screening procedures on models and patients.

5.5.2 The training programme on 'Cancer Epidemiology and Surveillance' (CanEST) implemented by ICMR-NCDIR was initiated in October 2021 and aims to strengthen

capacity building and training in cancer epidemiology and surveillance, leading to enhanced national and sub-national capacity for prevention and control of cancer in the country. The target participants for the course includes Principal Investigators, Co-investigators of PBCR/HBCR, state focal points for NPCDCS programme, oncologists, faculty of medical colleges and researchers, epidemiologists, medical officers, NGO personnel involved in cancer management, others interested in cancer research. The teaching sessions of the programme include discussions, programmed instruction, practical exposure to data collection and management, assignments, problem solving exercises, presentations/seminars.

5.5.3 About the hands-on trainings workshops conducted by NICPR, the Ministry listed the following:

- Hands-on workshop on “Screening of Common Cancers” for Medical Officers
- Hands-on workshop for Gynecologists in Colposcopy and treatment of CIN
- Hands-on workshop for Dentists in Oral screening and Tobacco cessation
- Awareness program for ASHAs and ANMs

#### **Atomic Energy Regulatory Board (AERB):**

5.6 The syllabus for radiation protection and safety is prescribed by Atomic Energy Regulatory Board (AERB) as per its one of the mandates, for incorporation in the training courses on medical / radiological physics related to radiotherapy practice. At present 26 institutions in the country are conducting courses such as M.Sc. in Radiological Physics/M.Sc. Medical Physics/Post M.Sc. Diploma in Radiological Physics/Post M.Sc. Diploma in Medical Physics. Candidates who have successfully completed this course are approved by AERB as Radiological Safety Officer (RSO), after their further assessment carried out jointly by AERB and Bhabha Atomic Research Center (BARC). These candidates also act as Medical Physicist in cancer hospital for commissioning & Quality Assurance tests of radiotherapy equipment, dosimetry treatment planning, etc. About 118 institutions are conducting courses for Diploma/Degree in Radiotherapy Technology who act as Radiotherapy technologist in cancer hospitals. As on date (June 2022) 2042 Medical Physicists and 4554 radiotherapy technologists are registered with AERB. Presently 541 radiotherapy institutions have been licensed by AERB for operation of radiotherapy facilities.

#### **Tata Memorial Center (TMC)**

5.7 Creation of human resources for cancer care and research for the country: largest output of students / trainees in cancer related areas in the country

- Specialists in surgical (general surgical oncology, head and neck, gynaecologic oncology, plastic surgery), medical (adult and paediatric), and radiation oncology
- Experts in public health, cancer research
- Patient navigators (Kevats), clinical research professionals
- Radiation technicians, radiographers, oncology nurses

5.7.1 There have been substantial increases in the number of students and trainees who have undergone training at the Tata Memorial Centre, with close to 1200 trainees currently.

5.7.2 In his written submission, the Director, Dr Boroah Cancer Institute (DBCi) mentioned that Cancer research in India should be contextual and relevant to the needs of the country. Reliance only on research done in high income countries should reduce as they differ in the types of cancers, the socio-cultural and economic context, and health systems. Medical

institutions across India should prioritize research in addition to patient care and education. He further mentioned that the Clinical Research Secretariat (CRS) and the Department of Atomic Energy Clinical Trials Centre (DAE-CTC) established in 1997 at the Tata Memorial Centre is an example of how creating the right infrastructural support can provide the environment for high quality research. Several globally practice-changing cancer clinical trials have resulted from this organizational initiative, which also conducts periodic training in research methods and Good Clinical Practice (GCP) for investigators.

5.7.3 Creating Clinical Trial Units (CTUs), academic Contract Research Organizations (CROs) and Institutional Ethics Committees or Review Boards facilitate the conduct of research by support for study design, biostatistics, data management, regulatory submissions and approvals, contracts and trial insurance. The components of a comprehensive CTU include clinicians with wide experience in conducting clinical trials, biostatisticians, trial and study management teams (clinical research coordinators, study monitors, clinical project managers, data managers), database management systems (personnel and software) and administrative staff. A robust ethics and regulatory framework is crucial to ensure good clinical research practices (GCP) and high-quality research conduct – establishing this well ahead of embarking on research is important. Organizational support should also include curation of core facilities, datasets, biobanks, and other resources that benefit multiple investigators, in particular those at early career stages. The National Cancer Grid every year convenes the International Collaboration for Research Methods Development in Oncology (CreDO) Workshop with an objective to train researchers in Oncology to develop trial designs.

5.7.4 The Director, DBCI informed the Committee that ICMR has started a pilot project “DHR-ICMR Advance Medical Oncology Diagnostic Services (DIAMONDS)” to create research infrastructure facilities. Similarly, Department of Bio-Technology, Govt. of India has introduced “**Biotechnology Industry Research Assistance Council (BIRAC)**” project to strengthen and empower the emerging Biotech enterprise to undertake strategic research and innovation. Many Oncology centres have received funding for site preparation to conduct clinical trial with the supports from pharmaceuticals industries.

5.7.5 The Department of Health Research (DHR) has a budgetary provision of Rs.3200.65 crores for the year 2022-23 for promotion of academic, training and research activities. He suggested that at least 20% of the total budget should be earmarked for the said objective in Oncology.

5.7.6 National Cancer Grid efforts in cancer research

- Developing and funding clinical trials in cancers common / unique to India – 11 trials funded so far
- Training in Cancer Research Methods – International Collaboration on Research methods Development in Oncology – CReDO workshop
- Virtual Research Boards – online mentoring for research studies
- NCG academic Clinical Research Organization (CRO)

**5.7.7 The Committee recommends higher funding allocation for organizations like ICMR, DBT and DST for clinical and translational research that has the potential to change the practice in India and the world and which results in Ayurvedic formulations. Higher funding can also lead to rigorous testing of other plant products for novel indications or to mitigate toxicity using the technical know-how and research innovations at ACTREC.**

## Academic Training

### 5.8 National Cancer Grid efforts in education / training:

- Continuing Medical Education – NCG National Cancer Library
- Discovery tool ‘Akshara’ – collates library resources from member centres
- Unique Educational Initiatives – “Traveling Schools” of Pathology and Oncology Nursing
- Massive Open Online Courses (MOOCs) available at [ncgeducation.in](http://ncgeducation.in)

5.8.1 TMC has also spearheaded cancer research in the country with several pathbreaking findings changing clinical practice globally – these have been recognized by plenary presentations at the top cancer conferences in the world. The research focuses on common or unique cancers in India with cost effective interventions. Some of these studies which have changed practice globally include the community-based screening of cervical and breast cancer using Visual Inspection with Acetic Acid (VIA) and Clinical Breast Examination (CBE), role of surgery in metastatic breast cancer, role of prophylactic lymphadenectomy in early oral cancer, chemoradiation in cervical cancer amongst others. The pre-eminent position of TMC in cancer research has been facilitated by the creation of a Clinical Research Secretariat and the Department of Atomic Energy Clinical Trials Centre (DAECTC), which supports researchers and facilitates the conduct of research in addition to training on the basics of clinical research methods.

5.8.2 Health care specialization in cancer may be available with qualification such as doctors with D.M. (Medical Oncology), M.Ch (Surgical Oncology) and M.D. (Radiation Oncology) who treat cancer patients in higher level tertiary care hospitals. Other Doctors such as General Surgeons, Gynecologists, ENT Surgeons etc. depending on the type and site of Cancer also treat in different hospitals. The number of oncologists who are MD Radiotherapy, DM Medical Oncology and MCH Surgical Oncology may be very few (about 2000) but several other specialties are involved in the diagnosis and management of cancer.

5.8.3 To increase the number of seats in Super specialty course in Medical Oncology, Surgical Oncology, Anaesthesiology and broad specialty course in Radiotherapy, the ratio of number of Post-Graduate (PG) teachers to the number of students to be admitted has now been increased to 1:3 for a Professor subject to a maximum of 6 PG seats per unit per academic year. Further the ratio of teachers to students has been revised from 1:1 to 1:2 for all MD/MS disciplines. Shortage of faculty is being addressed by the inclusion of DNB qualifications for appointment as faculty.

5.8.4 Replying to a query about the role of basic research and its translation for patient benefit, the TMC apprised the Committee that the fundamental goal of TMC as a Research Unit was to understand cancer in all its manifestations and find means to cure it. The ongoing road towards translation is grouped into (a) that have changed practice in the clinic; (b) products that have immediate relevance to the patients and can be cost- effective; and (c) novel and innovative targets and drugs with a clear translational components likely to enter preclinical studies in the next five to seven years.

5.8.5 To sum it can be stated that the following initiatives are required on cancer research:

- (i) Appreciation of major regulators like US FDA, EMEA, Japan, Australia etc in approving any new drug/molecule etc. in India;
- (ii) There needs to be better appreciation of global trials, efforts from global regulators in understanding data etc. and this would enhance speed of approvals and better

- care for our population; and
- (iii) Clinical trials and data generation efforts to be incentivized.

### **Collaboration with International Cancer Research Organizations:**

5.9 International Cancer Genome Consortium (ICGC) DBT India Project: India is one of the 7 founding members of ICGC (now 40 countries). Goal of ICGC is to provide new insights into cancer by comprehensive genomic characterization of 25000 paired tumor / normal tissue samples. After few consultative meetings, India chose Oral Cancer (Gingivo-Buccal) as cancer type. The India Project has collaboration between two centers –Advanced Center for Treatment, Research & Education in Cancer (ACTREC) at Tata Memorial Centre, Mumbai and National Institute of Biomedical Genomics (NIBMG) at Kalyani, West Bengal. At ACTREC, Patient recruitment, treatment & follow up; sample collection, biobank, HPV, functional characterization of novel genes & clinical correlation is carried out. At NIBMG Whole Exome / Genome sequencing and its bio-informatics analysis is being carried out. ICGC-India Project has established a dedicated bio-repository with best international practices at ACTREC and State-of-the-art high throughput Genome sequencing centre at NIBMG. Research findings have been communicated in Nature Communications, International Journal of Cancer & Scientific Reports.

5.9.1 ICMR has successful collaboration with European countries, European Union (EU), France, Germany and USA in area of cancer, ICMR-INSERM collaboration, Indo-German Collaboration on cancer research and ICMR/DBT/NCI-AIIMS and NCI-USA on cancer cooperation

5.9.2 An MoU has been signed between Department of Bio-technology (DBT), Govt. of India and Cancer Research UK for a Cancer Research Initiative: “Affordable Approaches to Cancer”. In furtherance to this MoU, DBT, Cancer Research UK and DBT / Welcome Trust India Alliance have now signed a tripartite agreement that sets out the terms and conditions by which the India Alliance will undertake grant-funded activities for the second and the third phase of the India-UK “Affordable Approaches to Cancer Initiative”.

5.9.3 Tata Memorial Centre, Mumbai collaborates internationally with National Cancer Institute (NCI), USA, Princess Margaret Cancer Centre, Canada, King’s College London, National Cancer Centre Japan, International Agency for Research on Cancer (IARC), France and International Atomic Energy Agency (IAEA) amongst other such collaborations. Similarly, some other cancer centres in the country also have international collaboration in the field of cancer research. NCI-India under AIIMS, New Delhi is such an example.

**5.9.4 The Committee appreciates the efforts of the Department of Biotechnology, ICMR and Tata Memorial Centre in collaborating with international organizations for cancer research and hopes that India-UK “Affordable Approaches to Cancer Initiative” shall bear fruit in the direction of taking cancer diagnosis and treatment to the last person in India.**

### **Status of research on India centric cancer centres in public and private sectors:**

5.10 The project on “Screening and early detection of cervical, breast and oral cancer in Cachar, Assam: a pilot project (2017-20),” includes training of the master trainers on screening and early diagnosis of common cancers by National Institute of Cancer Prevention and Research (NICPR), Noida in phase I. In the second phase, the front-line workers are

trained who would implement the screening program in the community. Through project on “Strengthening State Non-Communicable Disease Programme for Early Detection of Breast Cancer Involving Strategic Education and Awareness among the Women: a Joint Programme of State Government and ICMR-Desert Medicine Research Centre, Jodhpur, it is aimed to strengthen state cancer screening programme and develop a referral system for diagnosis and treatment of suspected cases at state medical colleges/ district hospitals. Keeping in view of high burden of breast cancer in country; ICMR has initiated project on “Comparative Study of Genetic, Clinical and Epidemiological Factors of Breast Cancer in Rural and Urban Area of India” in rural and urban women of north and south parts of country primarily looking at risk factors.

5.10.1 Gallbladder Cancer (GBC) is one of the commonest gastrointestinal malignancies, especially amongst females. There are regional variations shown in ICMR Cancer Registry data; gall bladder cancer is amongst first five leading sites of cancer amongst females in north and northeast population-based cancer registries whereas such is not the case in cancer registry data from other parts of country. The prognosis is poor with <10% of patients suitable for curative resection and an overall 5-year survival of <5%. The etio-pathogenesis is not well understood, and study of risk factors is thus very important. Three projects are ongoing viz: (i) Genomics of Gall Bladder; (ii) Pattern of Care and Survival Studies (POCSS) on Gall Bladder Cancer in Indian Hospital Based Cancer Registries and (iii) Incidental Gall Bladder Cancer and other Pre-malignant Gall Bladder conditions in India towards early detection of Gall Bladder Cancer.

5.10.2 North-East region of country is quite different from mainland in terms of lifestyle, genetics and dietary factors. The consumption of alcohol and tobacco is very high and different modes of consumption are practiced. As per ICMR’s Cancer Registry data; Mizoram is reported to have highest incidence of cancers of all sites in males and Arunachal Pradesh for all cancer sites in females. Risk factors are different in this part of country owing to different food habits. The proposal on “Comprehensive microbiome characterization in esophageal, stomach and nasopharyngeal cancers of North-Eastern India by Cachar Cancer Hospital and Research Centre, Silchar, Assam,” was initiated with aim of undertaking comprehensive microbiome profiling of esophagus, stomach and nasopharyngeal cancers and validate microbiome microarray findings with targeted NGS and qPCR-based testing. It is also proposed to correlate microbiome data with tumor stage, treatment response, prognosis, ethnicity and other clinic- pathological factors.

5.10.3 National Cancer Registry Programme (NCDIR-NCRP) runs the ‘Patterns of care and survival studies for cancers of the head & neck, cervix and breast’ (POCSS) at selected centres under the NCRP since 2006. The specific objectives of this study are to determine hospital-based patterns of care in terms of diagnosis and treatment estimate overall and disease-free survival of patients with these cancers. The results from this study will aid clinicians and public health experts in evidence-based decision making and contribute towards prevention, early detection and control policies and programmes. It will also enable hospitals to monitor and evaluate their performance in providing care to patients with these cancers.

5.10.4 The Patterns of Care and Survival Studies (POCSS) on Cancers in Childhood, Lymphoid and Hematopoietic Malignancies, other Gynecological Malignancies in Chennai, Bangalore, Thiruvananthapuram, Delhi and Mumbai is being conducted by ICMR-NCDIR in eight major hospitals. The objectives include (i) To estimate demographic and disease-free survival for Childhood, Hematolymphoid and Gynecological malignancies (except cervix

uteri). (ii) To assess the epidemiological and clinical determinants of survival for these three cancers.

5.10.5 A project was initiated in 2017 to generate reliable data on population-based cancer survival in cancers of the breast, cervix and head and neck; and survival based on clinical stage/extent of disease across the 25 Population Based Cancer Registries (PBCRs). Patients diagnosed in 2012 are followed up regularly (for at least five years from the date of the first diagnosis of cancer).

#### **CaResNER multidisciplinary programme, implemented by ICMR-NCDIR**

5.10.6 Monitoring survey of cancer risk factors and health system response in the Northeast Region of India: The study aimed to generate key cancer and other NCD related risk factors and health system response indicators in 12 Population Based Cancer Registries in 8 states of North-East India in a study sample of 23, 040 adults over 18 years. The survey was conducted between November 2019 and April 2021, and the pooled state findings were released as a report on World Cancer Day (4th February 2022).

5.10.7 The CaResNER programme aims to support capacity building in cancer research by announcing for a call for proposals since 2019. A total of seven projects that are working on scaling up of cancer prevention and control and health system strengthening are being funded.

5.10.8 Situational analysis of childhood cancer care services in India: The ICMR National Centre for Disease Informatics and Research (NCDIR), Bengaluru, assessed the present situation of childhood cancer care services in India, with a focus on availability, facility preparedness and capacity, treatment-related practices, and perceived barriers and facilitators in diagnosing and treating childhood cancers. The situational analysis was conducted between July and October 2021, using a cross-sectional survey design among tertiary level hospitals, secondary level hospitals, State Nodal Officers/NPCDCS officers and Civil Society Organizations/Non-Governmental organizations (CSOs/NGOs) in 26 states and 4 union territories (UT).

**5.10.9 The Committee feels that as research on India centric cancer centres are receiving a great impetus from the Government of India through the AYUSH Ministry, novel compounds from Ayush products and Ayurvedic formulations, other plant products can be rigorously tested collaboratively between Ayush institutes and other institutes having modern technical know-how and research innovations like ACTREC, IISc, IITs, NIPERs and such other institutes. This can be enhanced further by testing these products/ innovations on cancer patients attending both the AYUSH hospitals and modern allopathic hospitals in the setting of large trials which will be acceptable to people in other parts of the world.**

#### **Scope for public-private partnership in the field of academic training and research activities for treatment of cancer:**

5.11 The Ministry has informed that through the Glue grant scheme of the Department of Biotechnology public private linkages have been created between IISc, Bangalore; University of Mysore; IBAB, Bangalore and MSMF, Bangalore for a R&D project entitled 'Exploring Novel BCL2-specific Inhibitors against Leukemia and Lymphoma'.

5.11.1 The Ministry has also informed that the need for creation of research infrastructure in public and private sector is imperative and an important activity. DBT supported projects at

various universities and institutions have created the necessary infrastructure to carry out research activities pertaining to cancer research.

5.11.2 The Indian Cancer Research Consortium (ICRC) was established in 2019 under aegis of ICMR-DHR with aim to bring all the stakeholders working in cancer research under one umbrella that include researchers, health-care professionals, public health representatives/policy makers, international agencies, academic institutions about working together to conquer cancer. The main purpose is to facilitate better coordination at national and regional levels. The ICRC is poised to be India's only comprehensive cancer control coalition that is expected to enable brainstorming by bringing together India's cancer community and thus prevent, control, and reduce the cancer burden in India by identifying disease challenges being faced by health professionals and developing the ideal mix of interventions that make a difference. It is expected that research would be accelerated, especially in areas and programmes relevant for policy makers.

5.11.3 The purpose of cancer consortium is to identify, prioritize and respond to the research needs of the country for prevention, control and management of cancer in India. Specific Thematic Working Groups are constituted based on the strategic areas and draw upon a diverse set of competencies and knowledge. Seven Thematic Working Groups identified are: (i) Prevention and Epidemiology; (ii) Diagnostics; (iii) Therapeutics; (iv) Palliative Care; (v) Innovation and (vi) Clinical Trial. Technical Advisory Group is mandated to provide technical guidance and prioritize research topics with Director General, ICMR as chairperson. The Technical Advisory Group (TAG) also oversees establishment of ICRC and periodically review its activities vis-à-vis action plans. The Technical Advisory Group (TAG) facilitates the development and support of trans-institutional efforts and ensure research is tuned to address programme gaps & challenges. Government agencies (MOHFW, DGHS, ICMR institutes, PGI Chandigarh, AIIMS, Delhi); academic institutions (Indian Institute of Science, Bangalore, Institute of Bioresource and Sustainability Development [IBSD], Assam); international agencies (WHO, National Cancer Institute, USA), industries (Biocon, Pfizer, Thermofisher), etc are part of various committees thus constituted.

5.11.4 A high-level Leadership Group (LG) with the Hon'ble Union Minister for Health & Family Welfare as Chair would be constituted to provide the overall advice and direction to Indian Cancer Research Consortium (ICRC). Following call for proposals; the project review committees were constituted to review proposals and short-listed proposals are under process for funding.

5.11.5 The National Cancer Grid started in 2012, is a network of major cancer centres, research institutes, patient groups and charitable institutions across India with mandate of establishing uniform standards of patient care for prevention, diagnosis and treatment of cancer, providing specialised training and education in oncology and facilitating collaborative basic, translational and clinical research in cancer.

**5.11.6 The Committee observes that Public-Private Partnership in the field of cancer research activities should be taken up on the format of the National Cancer Institute, USA. The Committee hopes that it will encourage investigators to come forward and do research based on the cancer scenario in India and therefore will be more useful in the Indian clinical setting. This should not be confined to the research activities only, but provision should also be there for support for publication in journals as well as circulation of results of these research activities.**

**5.11.7 The Committee is given to understand that some Institutes of Eminence in the private sector are conducting research activities in the field of cancer - but that is confined to the aspect of basic sciences only. The Committee opines that it needs to be translated to the clinics for the benefit of the patients. The government should encourage agreements between these institutes in the private sector and hospitals in the public sector treating cancer patients where footfall of cancer patients have been found to be massive so that trials can be carried out resulting in “real-world” data useful for the cancer scenario in India.**

5.11.8 India Cancer Research Consortium (ICRC) has been established under the aegis of ICMR-DHR in 2019 with the aim of creating a nationwide network of scientists, public health/programme officers, academia and civil society engaged in cancer research and developing a prioritized national cancer research agenda involving different stakeholders.

**5.11.9 The Committee further recommends that the government should devise strategies for linkages of cancer research with various industries/companies for funding under Corporate Social Responsibility (CSR).**

**Need for creation of national and international platform for knowledge sharing and technology transfer pertaining to cancer care and treatment:**

5.12 ICMR is member of Technical Advisory Committee of International Agency for Research on Cancer (IARC). It also provides cancer registry inputs to GLOBOCAN (WHO). ICMR has existing memorandum of understanding with Europe, France, USA and Germany as mentioned above for research collaboration. India is also a member country of International Agency for Research and Cancer (IARC) and World Health Organization.

5.12.1 Govt. of India also ratified the WHO Framework Convention on Tobacco Control (WHO FCTC), the first ever international public health treaty focusing on the global public health issue of tobacco control. WHO-FCTC provides for various measures to reduce the demand as well as supply of tobacco.

**5.12.2 The Committee is given to understand that at present, cancer centers like Tata Memorial Hospital and ACTREC, Mumbai, Dr. B Borooah Cancer Institute, Guwahati and other such centers have MoUs (at the organizational level) with national and international organizations for promotion of academic and research activities. However, the Committee notes that for an all-inclusive platform, the National Cancer Grid shall take a bigger role for creating such a platform for collaborative/exchange program activities.**

**Make in India Approach in Technology Innovation in Oncology:**

5.13 Bhabha Atomic Research Centre (BARC) has designed and developed ‘Bhabhatron’ Tele-cobalt machine which is 50% of the cost of imported machine. The Bhabhatron machine has been upgraded with Multi Leaf Collimator (MLC) for advanced treatment. A new Linear Accelerator machine has been developed in India. With Industry support and collaboration from BARC, IITs, and similar institutions, technology innovation is possible. Considering the huge demand for radiotherapy machines, there is potential to develop indigenous Tele-cobalt and Linear Accelerator machine. There is already indigenously made Conventional Simulator and Mammography machine. The Govt. of India can explore tie-up with industry to manufacture costly diagnostic equipment like CT Scan, CT Simulator, Gamma Camera Machine, Ventilators, Digital X-ray machines, Ultra Sonography machines,

etc. which are not only integral component of Oncology Centre, but also part and parcel of general and super specialty hospitals.

**5.13.1 The Committee expresses its concern that the National Cancer Registry Program covers just 10% of the population of India as of 2020 data and feels that the data is very crucial in the research activities. The Committee, therefore, recommends that the Government should build a unified database through systematic collection, analysis and use of epidemiologic data which will further help to define sustainable frameworks for Cancer control in the community and help in bringing out the desired researches. The Committee feels that through Cancer registries, the systematic tracking of Cancer outcomes can contribute to incredible advances in understanding the epidemiology of Cancer. Even greater potential exists in tracking the costs and benefits of therapies, stage of diagnosis, follow-up data on outcome and long-term survival after the Cancer diagnosis in a real-world setting.**

**5.13.2 The Committee expresses the imminent need to build interoperability between the population based and hospital-based Cancer registries by adopting digitization of healthcare, which will improve the quality of data collection through standardization and by removing the duplications.**

**5.13.3 The Committee feels that clinical trials of investigational new cancer drugs remain disproportionately concentrated in High Income Countries and the under-representation of racial and ethnical population such as India reduces the generalizability.**

**5.13.4 The Committee notes that the gaps in the research from Indian perspective include the scarcity of reliable data, a paucity of clinical trials and lack of an environment conducive to research in academic institutions (Public), including research infrastructure, trained human resources, funding and willingness to conduct the research. The Committee, therefore, recommends that efforts to strengthen research capacity in India should be expanded to individual, organizational and institutional levels as working on all three levels is more likely to yield long-term results. The Committee also feels that building cancer research network and collaboration can work efficiently on shared problems and common research priorities locally and globally.**

**5.13.5 The Committee observes that several interventions are required for fostering an innovation-based ecosystem in the country.**

### **National Policy to Catalyse Research & Development and Innovation in the Pharma Sector in India**

5.14 The Committee is given to understand that India is an attractive investment destination for R&D. Hence, there is a need for a National R&D Policy's whose intent is to effectively improve the investment ecosystem for the research-based pharmaceutical industry, through seeking to coordinate policies that range across strengthening regulatory frameworks that facilitate innovation and research in product development; incentivizing investment in Innovation; and an enabling ecosystem for innovation and research. The objective must also include facilitating faster introduction of innovative therapies for patients in India as an objective of regulatory simplification.

**5.14.1 The Committee recommends that for establishing a meaningful R&D ecosystem in India, it is critical to have a robust IP environment which does not allow frustration of patents. An effective IPR regime is an essential pillar to promote innovation. Therefore, IP protection and enforcement must find place in the National R&D Policy.**

### **Harmonisation of Regulatory Norms**

5.15 India has undertaken regulatory reforms, including adoption of New Drugs and Clinical Trials Rules 2019 (NDCT 2019), with the goal of strengthening the regulatory regime and reinvigorating clinical research. Strong, transparent and predictable regulatory frameworks are essential to protecting patients as well as to promoting globally competitive innovative and generic pharmaceutical industries. However, NDCT 2019 include significant ambiguities and several discriminatory provisions, which create uncertainties in the regulatory process for clinical trials and threaten the overall clinical research environment in India.

**5.15.1 The Committee feels that the Indian pharma sector needs greater alignment with the rest of the world - particularly with the developed western countries that are the largest export markets for Indian companies, and the peer group of BRICS nations that are at a somewhat similar level of development and regulatory competency. India can acquire a higher degree of harmonisation by adapting their rules and regulations to guidelines developed by the International Conference on Harmonisation (ICH) which aims to find a way to reduce global drug development time and costs while enhancing patient safety and quicker access to new medicines.**

### **Adopting ‘Reliance Pathway’**

5.16 Regulatory Reliance is being actively promoted by organizations such as World Health Organization (WHO), the Pan American Health Organization (PAHO) and the European Medicines Agency as a mechanism for National regulatory Authorities (NRAs) to better manage resource capacity issues whilst simultaneously strengthening regulatory systems. The proposed process will avoid duplication in generating data & the lead-time required for approvals will be shortened to minimum 3 Months.

**5.16.1 The Committee feels that adopting ‘Reliance Pathway’ will ensure faster and expedited approval in India as well and which in turn will ensure the drug reaches the patients faster and at the same time by when it will reach the overseas patients as the review process will be ensured in parallel. Adopting Reliance pathway in India, which considers the review of key countries and clears the innovative drugs in a very short time, which many countries in South Asia and Latin America have already adopted**

### **Stable, Predictable Patent Environment and Improved Patent Enforcement**

5.17 India’s legal and regulatory systems pose procedural and substantive barriers at every step of the patent process, including: impermissible hurdles to patentability posed by Section 3(d) of India’s Patents Act, 1970, patent grant delays due to cyclic filings of pre-grant oppositions followed by rampant post-grant opposition proceedings, onerous patent application disclosure requirements and conditioning patent grant on unclear and subjective access and benefit sharing requirements that disproportionately affect foreign patent applicants. Not only is this a concern in the Indian market, but also in other emerging

markets that may see India as a model to be emulated. Patent applicants continue to face rejections under Section 3(d), infringement due to improper marketing authorization for generic versions of on-patented drugs, and the threat of compulsory licenses (CLs), all of which demonstrate that much work needs to be done to improve the patent environment in India.

5.17.1 Under the existing laws in India the marketing and manufacturing approvals are not transparent or coordinated between federal and state agencies. Indian law allows the Central Drugs Standard Control Organization (CDSCO) to approve third-party manufacturers to commercialize copies of innovator products, regardless of whether those products infringe on an innovator's patent(s). After four years of the medicine's first approval in India, a license from any of the state drug regulators to manufacture and market the product in India suffices – resulting in irreparable harm to patients, innovators, and other follow-on producers. Not only do such products violate patents granted in India, they may also potentially threaten patient safety. A Central Notification System may be provided where non-commercial information in respect of applications filed before the CDSCO/State or UT FDAs for obtaining marketing/manufacturing license such as name of the applicant; name of the drug; dosage form; composition of the formulation; pharmacological classification of the drug; indication etc. are made available in public domain and be accessible to all. This may be achieved by first linking of the SUGAM Portal at Centre & State level. Such a notification system does not require any amendment to legislation/s and will address the difficulty faced by the innovators in tracking potential infringers and approaching courts in a timely manner.

#### **Exempting patented drugs from National List of Essential Medicines:**

5.17.2 There needs to be a predictable and transparent pricing regime in the country. Patented drugs should not be included under the NLEM as their price fixation will nullify the IPR so granted. The Government should consider inclusion of only those drugs in the NLEM that meet the criteria of 'essentiality'.

#### **Human Resource Planning**

5.18 The Committee has been informed that there are about 38,000 post-graduate seats in the country in various disciplines. However, the percentage of seats in radiation in oncology, super-specialty courses and M.Sc. in oncology nursing is only 0.75%, 9.53% and 0.26% respectively.

5.18.1 The Committee has also been informed that the country lacks adequate number of health care professionals and different cancer specialized centres are absent in the many existing Cancer Care Centres. The available experts are being recruited at Private hospitals at a much higher remuneration.

5.18.2 The current scenario with respect to trained manpower is indicated as under:

Medicines (The total number of seats in MD / MS courses (37,392) and Diploma Courses across all branches of 922) (as per NMC website )	: 38,314
Number of Radiation Oncology (PG/Diploma) seats	: 286
Percentage of PG / Diploma seats (Radiation Oncology)	: 0.75%
Total number of seats for Super Specialty Courses in various disciplines	: 2929

Super Speciality courses in various disciplines of Oncology	: 279
Percentage of super specialty seats in Oncology	: 9.53 %
Total number of seats in M.Sc Nursing (INC website 2021)	: 12 707
Total number of seats for M.Sc in Oncology Nursing	: 33
Percentage of M.Sc. in Oncology Nursing seats	: 0.26 %
Total number of seats of MSc / PG Diploma / Radiological Physics	: 200

**5.18.3 The Committee is of the view that there is a need of increasing the number of postgraduate seats and Super Specialty Seats in Oncology. The Committee, accordingly, recommends the Ministry of Health and Family Welfare to increase the number of seats in various disciplines of oncology along with increase in seats in MD in radiotherapy, M.Sc. in radiological physics etc. The Committee also recommends the Ministry to explore the introduction of two years' post graduate fellowship programme in various disciplines in oncology that are duly accredited by National Medical Commission.**

**5.18.4 The Committee further notes that there is lack of adequate manpower to make the cancer centres fully operational. In the absence of specialized healthcare force, many super specialities remain defunct even after the establishment of the physical infrastructure. The Committee accordingly recommends the Ministry of Health and Family Welfare to take effective measures to fill the sanctioned posts in these Cancer Care Units. To avoid such delays in making the centres fully operational, the Ministry must make manpower provision at the time of sanctioning a project. The Committee is of the view that the State Governments must also play an active role in ensuring that the manpower in State-run Cancer Institutes is adequate. The Committee also notes that very few institutions conduct technical courses that produce paramedics and technicians that can take care of increasing load of cancer patients. The Committee accordingly recommends the Ministry to increase such courses as the trained manpower is fundamental to providing value-added-services to the patients which will help improve their quality of life.**

**5.18.5 The Committee also recommends the Ministry to explore 25% reservation for in-service candidates for degree courses with agreement to serve cancer Institute for minimum 5 years. The Committee also recommends the Ministry/National Medical Commission to revisit the Teacher, Student ratio to accommodate PG/Super speciality students. The Ministry must also increase the number of hospital beds in the existing hospital to meet the NMC requirement for increase of seats. The Government may also explore providing stipendiary supports to all centers conducting PG/Super specialty courses.**

**5.18.6 The Committee appreciates the Shared Hospital Income (SHI) scheme of Tata Memorial Centre wherein approximately 12 to 15% of overall hospital income is shared amongst medical staff. The Committee recommends the Ministry to implement similar Scheme across other cancer centres to retain qualified staff.**

5.18.7 The Human Resource Requirement in the hub and spoke is as follows:

<b>HUB</b>	
Category	No.
Medical	185
Scientific	126
Technical	330
Nursing	393
Administrative	152
Auxiliary	117
Total	1303

<b>SPOKE</b>	
Category	No.
Medical	61
Scientific	42
Technical	110
Nursing	131
Administrative	51
Auxiliary	39
Total	434

**5.18.8 The Committee notes that cancer cases in India are diagnosed at a later stage which is a major cause of high mortality to incidence ratio and increase in cancer care expenditure. The Committee strongly believes that a strong network of cancer care centres across the country would facilitate early diagnosis of cancer cases and greatly reduce the burden of cancer cases in India. The Hub and Spoke Model is an efficient distribution model of providing comprehensive cancer care by creation of hubs and spokes in all the States of the country. The Committee notes that TMC has worked in close contact with the State Governments to create hubs and spokes in States. The Committee believes that such collaborations will enable in further strengthening the cancer care infrastructure along with knowledge, skill and resource sharing. The Committee appreciates the work done by TMC and DAE and strongly advocates the need for establishing government funded hub and spoke model of cancer care across States. The Committee further believes that ensuring adequate human resource in Cancer centers under the hub and spoke model is also crucial for complete operationalization of the Centers.**

5.18.9 The Director, Dr B Borooah Cancer Institute, while reflecting upon the current scenario of Trained Manpower in the country mentioned that at present the total number of seats in MD / MS courses (37,392) and Diploma Courses across all branches of Medicines (922) (as per NMC website) is 38,314 and the number of Radiation Oncology (PG/Diploma) seats is merely 0.75% i.e. 286. Similarly the total number of seats for Super Specialty Courses in various disciplines in the country is 2929 and the Super Speciality courses in various disciplines of Oncology are 9.53 % of the total seats i.e. 279. The total number of seats for M.Sc in Oncology Nursing is 33 i.e. 0.26 % of the total number of 12707 seats in M.Sc Nursing. The total number of seats of MSc / PG Diploma / Radiological Physics is 200.

**5.18.10 The Committee is given to understand that, TMC being the pioneer institute in cancer treatment, research and training, at present trains 60% of the country's workforce in cancer diagnostics and treatment and most of the researches in the field of oncology have also come from the TMC. The Committee observes that the number of oncologists, super specialists and nursing staff being trained at present is not enough to cater to the present need. The Committee further feels that with the plan of the government to spread the Hub & Spoke model in the aegis of TMC & NCG, the country would require a multiple number of oncologists as well as cancer caregivers in the next five years. The Committee is of the considered view that there is an imminent need to increase the academic training capacity to cope with the present and future requirements of oncologists as well as the caregivers.**

#### **Chitranjan National Cancer Institute(CNCI), Kolkata**

5.19 In response to the question as to what further steps can be undertaken to improve research in oncology in relation to cutting edge technology or through process and use of scientific method in a rigorous ways, the CNCI, Kolkata enumerated the following steps–

(i) Continuous up-gradation of human resources: For quality research, qualified, competent human resource with proven track record in their respective field is essential. Initiative has been taken to revise the Recruitment Rules to recruit the qualified research personnel not only at entry level but in all pay levels (lateral entry), keeping National and International norms in mind.

(ii) Creation of good Research environment: Institutional Academic committees are working to improve the research environment to promote collaborative research by regular discussion between clinician and research personnel by organizing meetings, seminars, workshops etc. Emphasis may be given in collaboration with private sectors, like, Pharmaceutical Industries to propagate drug based research and trials. Assessment meetings are also conducted in student and faculty levels in presence of external experts.

(iii) State-of-Art Instrumentation: Procurement and maintenance of sophisticated instruments related to genomics, proteomics, metabolomics those are essential for modern cancer research are maintained at CNCI and procurement process of several high end instruments are initiated.

(iv) State-of-Art Animal facilities with imaging: Refreshing of animal colonies is started. Proper infrastructure to maintain nude/SCID mouse is developed with Individually Ventilated Animal Caging Systems and in vivo imaging facilities.

(v) Development of co-operation and collaboration between Researcher and Clinicians: Clinicians are taking part in research projects with their views and research questions

experienced in Clinic. Both intra- and extra- institutional collaboration will be entertained. Development of Intellectual property is shared with participating faculties.

(vi) State-of-Art Library: Library is renovated and reorganized with all necessary facilities, like, e-books, e-journals, new softwares along with existing printed versions of books and journals.

**5.19.1 The Committee endorses the views of the CNCI and recommends that to improve the research quality in the country, the Government must ensure creation of good research environment, sophisticated instruments, collaboration of researchers and clinicians and a state of the art library in all the institutions conducting research in cancer diagnostics and treatment.**

5.19.2 In response to the question about the types of cancer treatment and research projects that can be collaborated more with National and International organisations for early detection, cost-effective treatment and betterment of cancer patients the CNCI replied that visual inspection on acetic acid (VIA) for cervical cancer screening is included in the existing national guidelines on NPCDS. VIA is a simple, cheap and affordable test to detect the white lesions of cervix which requires further management. The drawback of VIA test is, if not performed by a trained person, it can lead to high unnecessary referral and thus overtreatment of benign conditions of the cervix. As a regional cancer centre, CNCI can be appointed as the training centre of eastern region of the country, where regular manpower training and quality control of the screening test will be done. CNCI has been working on the field of cervical cancer prevention for last 20 years, thus having a huge network and accessibility to interior and remote parts of west Bengal. CNCI has played a key role in manpower training for both India and overseas.

5.19.3 CNCI also has an existing research wings with various research activities going on at molecular level of various human cancers. Being the regional cancer centre, many uncommon cancers has also been reported and can be of research interest. The department of palliative care and treatment is well established and thus incurable cancer cases can also get the benefit of cancer care.

5.19.4 Regarding the problem being faced by the CNCI in the field of training and research activities and the steps to combat the same, the CNCI mentioned the lack of adequate infrastructure for carrying out advanced cancer research and trained personnel; loss of trained and knowledgeable manpower in the Faculties and necessary financial support.

5.19.5 To combat these issues the CNCI suggested recruitment of knowledgeable Faculties/personnel, financial support from Institute as well as Extra Mural Research Project Grant, development of advanced research techniques related to genomics, proteomics and metabolomics of cancer biology, development of Immune compromised mice for Anti-cancer drug screening and encouragement of collaborative research with other Research Organisations and Universities/Institution in India and abroad.

5.19.6 Furnishing the details of new drugs/medicines developed at the Institute in the last five years for treatment of cancer and its integration in the treatment, the CNCI mentioned that a glycoprotein molecule is identified and characterized in neem leaf, termed Neem Leaf Glycoprotein. Extensive research on this molecule (50 publications in peer reviewed journals) proved its safety and efficacy for human use. They informed that isolation process has been patented and collaboration with Pharmaceutical industry is needed for its Clinical translation.

5.19.7 They further mentioned that different cancer chemo preventive phyto-chemicals are isolated from Black Tea, Turmeric, Swertiachirata, Clove, Lupeoletc and their bio-activity are tested in different cancer models; synthetic Chemo Preventive Drugs and Anti-angiogenesis molecules are developed and characterized and Gold Nano Particles using different Anti-cancer drugs are formulated and tested.

5.19.8 The department itself is imparting PG (MD) course in Radiation Oncology as the first Department in North East including Assam since 2001. Number of PG intake- 4 PG students per year – 50% students from North East States, another 50 % come from All India Quota (from the rest of the country). The PG (MD) course is recognized by MCI/NMC. So far more than 56 Doctors had been awarded MD (Radiation Oncology) specialists from many states of the country. Now all them are working across the country as faculty in medical Colleges, as Clinicians in many reputed cancer hospitals. Even, few students went abroad after passing MD for job. RCC has been conducting training programme of doctors, nurses and community health officers related to the cancer patient care in Primary Health Centres(PHC)& District hospitals in the field of day care chemotherapy, nursing care of cancer patients and palliative care of terminal cancer patients.

**5.19.9 The Committee observes that cancer research in India should be contextual and relevant to the needs of the country. Reliance only on research done in high income countries should reduce as they differ in the types of cancers, the socio-cultural and economic context, and health systems. The Committee recommends that all the medical institutions across India should prioritize research in addition to patient care and education as is being done at TMC.**

5.19.10 Replying to a query regarding the key concerns in the field of research, CNCI, Kolkata informed that lack of clinical, translational and community based research is a concern area and suggested that creation of a scientific committee to overlook the projects can play an important role.

5.19.11 The Institute mentioned that in the clinical sector the key concern is lack of clinical audit system and mentioned that research faculties are regularly assessed keeping following facts in view: 1. Evaluation of Individual work, training, publications and patents 2. Assessment of nature of work to allocate further budget 3. Assessment of whether the project is goal oriented and the level of achievement till now. Accordingly, a meeting was organized in the year 2018 under the Chairmanship of Prof. Siddhartha Roy, Director, Bose Institute, Kolkata and a meeting of an Expert Committee on Evidence-based evaluation of Scientific Officers of CNCI, Kolkata was held on 9th November, 2021 under the Chairmanship of Dr Maqsood Siddiqi, Ex-Director, CNCI, Kolkata, Ex Director, Bose Institute, Chairman, CFI, Kolkata. According to the Report given by the Committee measures were taken. In addition, Research scholars were regularly assessed for their performance by Academic Committee in the presence of external expert.

**5.19.12 The Committee notes the initiatives taken by the CNCI in the field of research for cancer treatment by taking several measures for promoting clinical research and recommends that such initiatives and measures should also be replicated in all the government institutions to boost the research and outcome in the country.**

### **Department of Atomic Energy**

5.20 The Clinical Research Secretariat (CRS) and the Department of Atomic Energy Clinical Trials Centre (DAE-CTC) established in 1997 at the Tata Memorial Centre is an example of

how creating the right infrastructural support can provide the environment for high quality research. Several globally practice-changing cancer clinical trials have resulted from this organizational initiative, which also conducts periodic training in research methods and Good Clinical Practice (GCP) for investigators.

5.20.1 Creating Clinical Trial Units (CTUs), academic Contract Research Organizations (CROs) and Institutional Ethics Committees or Review Boards facilitate the conduct of research by support for study design, biostatistics, data management, regulatory submissions and approvals, contracts and trial insurance. The components of a comprehensive CTU include clinicians with wide experience in conducting clinical trials, biostatisticians, trial and study management teams (clinical research coordinators, study monitors, clinical project managers, data managers), database management systems (personnel and software) and administrative staff. A robust ethics and regulatory framework is crucial to ensure good clinical research practices (GCP) and high-quality research conduct – establishing this well ahead of embarking on research is important. Organizational support should also include curation of core facilities, datasets, biobanks, and other resources that benefit multiple investigators, in particular those at early career stages.

5.20.2 In response to the question whether there are joint projects in Cancer at the National and International Level, the Tata Memorial Centre informed that TMC and the NCG is involved in several joint projects at the national and international levels. The NCG resource-stratified evidence-based management guidelines work towards uniformity of care by linkages to the AB-PMJAY scheme; several potentially practice-changing clinical research studies are underway with participation from several cancer centres and research institutions.

5.20.3 They further informed that internationally, TMC collaborates with the National Cancer Institute, US, Princess Margaret Cancer Centre, King's College London, National Cancer Center Japan, the International Agency for Research on Cancer and the International Atomic Energy Agency.

5.20.4 Additionally, basic scientists at ACTREC have several international collaborations under joint funding schemes such as Indo-UK, Indo- German, Indo-US, and others. They also have joint research collaborations with many Indian institutions such as IIT Bombay, IISER, IISc, and others.

5.20.5 In response to the query whether TMC faculty and staff are trained in developed countries for specific needs, the TMC informed that medical and scientific faculty at TMC are supported for international conferences/ workshops /training in areas of their expertise depending on institutional needs. In addition, they are supported for training in translational research at the King's College London for the MRes (Translational research) one-year program. They further informed that some of the faculty is already internationally trained. The TMC has an MoU with King's College London, through which every year they send 2 to 3 junior staff to undergo one-year of training in research (M Res). After completing three years of employment, TMC staff can apply for deputation abroad for one to two years of training in specialized areas, approval for which is given after discussion in the Collegium. After the first year of probation, all the permanent staff is eligible for attending 1- 3 (depending on their grades) International Meetings which help gain knowledge from International Faculty and also helps them in interacting with International peers and develop collaborations.

5.20.6 They further apprised the Committee that the delegation of TMC doctors and scientists visited 10 of the world's most renowned cancer research centres (in USA, Europe and Asia)

to draw up a plan for next-generation research program at TMC, with support from Tata Trusts. The report of this delegation is available and has been instrumental in planning the Centre for New Biology project at ACTREC/TMC.

**5.20.7 The Committee is given to understand that TMC research has resulted in practice- changing protocols that reduce cost and are said to be a policy for the country, however the Committee feels that the opening of TMC centres in various parts of India will stimulate the percolation of practice-changing results in various parts of the country. Moreover, the large cancer workforce being trained at TMC will help to disseminate the evidence-based cost- effective solutions that have been discovered at TMC. The Committee further recommends that the Government should focus on opening more research centres throughout the country and earmark 20% of the research budget on oncology.**

#### **Bhabha Atomic Research Centre (BARC)**

5.21 The TMC in their written submission to the Committee mentioned that DAE's research efforts have started yielding results in making affordable Cancer care. Bhabha Atomic Research Centre (BARC), a constituent Unit of DAE has developed products for affordable cancer diagnosis & treatment.

**5.21.1 The Committee appreciates the efforts of the scientists at BARC in developing products for affordable cancer treatment and notes that the indigenously developed products by BARC is made available at fraction of the imported cost. The Committee recommends that the government should encourage more such researches by providing more opportunities and funding to the scientists. Research should also be prioritized for early detection of cancer cases so that the spread of the disease can be nipped in the bud and lot of human and financial resources of the country is saved. The number of research is of paramount importance in the present context because the number of new cases and types of cancer is growing. If the scientists are able to develop diagnostics for multiple types of cancer at an affordable price the vast Country like India can be better placed for checking this growth trajectory.**

#### **Kidwai Memorial Institute of Oncology, Benaguluru**

5.22 The Kidwai Memorial Institute of Oncology submitted that there is a strong evidence of correlation between research activity and good patient outcomes. However, cancer research in developing countries including India hasn't really picked up to the required levels. In developed countries, cancer research networks include secondary centres and community outreach; whereas in India, most cancer research work is concentrated in tertiary cancer centres and specialized institutions of biomedical science. While there are many good cancer research institutes in India; very few offer comprehensive research covering all domains. Most of the existing and upcoming infrastructure is focused on cancer treatment with lesser priority on cancer research. Moreover, the rising burden of cancer puts a major strain on productive research time of clinicians and their staff. There is a need to have an advanced cancer research institute which will cover various aspects of research pertaining to local context, given the similarities in population and homogenous habits in the region. To address the unmet needs of research and to influence national policy for cancer; KMIO is setting up a state-of-the-art research hub.

## **Amrita Institute of Medical Sciences**

5.23 The Amrita Institute of Medical Sciences in their written submission to the Committee submitted that Research should be divided into basic science research and clinical research with special incentives for researchers. A better publicity for the research funding available from different bodies should be considered so that more researchers are tempted to jump into this field. Another area which needs promotion on a national level is encouraging clinical trials and public participation in clinical trials. This needs to be promoted in a big way so that more patients with advanced cancers can benefit. In India there is large number of cancer patients receiving treatment. However, unfortunately there is only minimal India data or protocol based on Indian patient experiences. Most of the protocols are based on Western patient data and the toxicity profile is not similar in our patient population. Hence, many times there is adhoc reduction of dose in Indian patients from western protocol to reduce toxicity, however the impact on outcome is less analyzed.

5.23.1 The Institute expressed the need to incentivize research ideas, promote research-based approach in our own patient population. Research initiatives need to be first initiated in academic hospitals and medical colleges as the acceptability and understanding of research ideas are better in these institutes. In primary and district level hospitals, patient data need to be collected to understand the prevalence of disease and outcome measures.

## **Jawaharlal Institute of Post Graduate Medical Education and Research, Puducherry**

5.24 The Jawaharlal Institute of Post Graduate Medical Education and Research, Puducherry in their written submission submitted that despite having over 1 million new cases of cancer per year, the research output in India is much behind nations like USA, Europe, Australia and China. To improve the research scenario the research should focus on problems relevant to our country, cancer which are common here as well as presentations which are unique here. Research should be on issues like the unique genetic and epigenetic signatures of cancers in India and the pharmacogenomic differences. Also, there are very few cancer drugs which are primarily developed in India, the regulatory environment requires a change to encourage new drug development, indigenous development will reduce the cost of drugs. The Government through relevant bodies like BIRAC, DBT, and DST should provide more support for development of real world evidence (RWE) as many cancers are rare and it will be difficult to have randomized trials for all cancers.

**5.24.1 The Committee also recommends that International Collaboration on Research methods Development in Oncology (CreDO) workshop should play the major role of research in cancer diagnostics and treatment by bringing the mix of clinician-researchers, trialists and statisticians together. The Committee feels that NCG funded multicentric collaborative research is also expected to bring transformation in the protocol of cancer treatment.**

## **Integrated Health & Wellbeing (IHW) Council on promoting research in cancer**

5.25 The Integrated Health & Wellbeing (IHW) Council in their written submission to the Committee suggested the following steps for promoting research in cancer:

- (a) Issuing a regular and detailed National Cancer Guidelines: At present there are official guidelines in the form of those published by Indian Council of Medical Research and the National Cancer Grid, yet however, they are still not as many detailed and up-to-date guidelines in India as is required. The current situation is

such that these guidelines are updated once in few years; hence, the need to is to develop ones that update in real-time or once every year, on a regular basis and that which is based on Indian specifications and experiences.

- (b) Proper implementation of existing guidelines: Given the low awareness about the NCG guidelines, there is a need for the capacity building work to be directed towards propagating and promoting awareness and adherence to these national guidelines.
- (c) Health Technology Assessment is a crucial tool for evidence-based decision making for health care benefits that has proven to be beneficial in the past in evaluation and standardization of healthcare interventions, such as HTA for Cervical Cancer that concluded visual inspection with acetic acid (VIA) every 5 Years is the most cost-effective cervical cancer screening option. Similar HTA implementation could also be made in the space of nationwide screening drives for common cancers such as oral cancer to assess cost-effectiveness and most optimal screening time frame. It could also be used as a potential tool to gauge the impact of several cancer care policy decisions that are already being implemented.
- (d) Research into standardizing screening for cancers: Screening of several cancers forms the basis of early detection and intervention. However, for certain types of cancers e.g., cancer of gallbladder, thyroid, corpus uteri have no definitive directly replicable models for early detection through effective screening mechanisms.
- (e) Clinical trials as per Indian context: Clinical research protocols and clinical staging for several types of cancer are done as per the international and standard guidelines. However, their applicability in Indian context calls for a detailed review and investigation. Further, clinical trials that encourage de-escalation of care without compromising outcomes should be encouraged.
- (f) Restarting research into the environment carcinogen testing units: Through cancer registration and thorough scrutinization of the data obtained from registrations we have been able to understand modifiable risk factors. One such important modifiable risk factor is that of Environment Carcinogen that significantly contributes to the uptrend of cancer burden. The concept of Environmental Carcinogen Testing Units (ECTU) was introduced to understand the role of environmental carcinogens in the aetiology of major cancers in India. However, due to budgetary constraints only suggestions were made to individual scientists. India being the 6th largest economy and 5th most resourceful country needs to allocate funds and reignite initiatives like ECTU for preventing the rise in cancer burden.

**5.25.1 The Committee recommends that India specific research must be funded and encouraged to ensure that treatment models and therapies that are developed are done so based on Indian variations and not western ones. The Committee feels that research on innovative therapies, more effective drugs with fewer adverse effects, repurposed drugs, pharmacological combinations, and more is necessary because modern treatments are exceedingly expensive; and India-centric research on such issues can help cut down costs of treatments. The Committee further recommends the Ministry to carry out more research and studies on prevention, early diagnosis and screening of the different types of cancer.**

## CHAPTER-VI

### CANCER CARE PLAN, RESEARCH & MANAGEMENT IN AYUSH

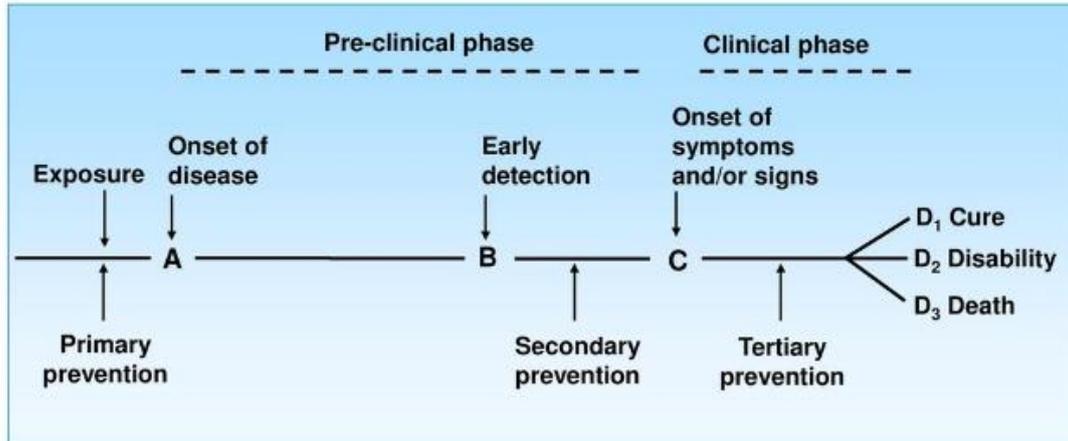
6.1 The increasing incidences of cancer cases in the country and the constraints in access to quality and affordable cancer care starting from early screening, detection, availability of proper treatment in particular and the health infrastructure in the country in general trigger inquisitive questions with respect to treatment through conventional medicine, high cost of treatment, limited access to cancer treatment, lack of adequate facilities for screening and detection, failure of treatment due to detection in the advanced stages of the cancer, alternative system of medicine to compliment the conventional system of treatment in better management of cancer etc. Besides that, the physical, mental, emotional and financial toll make the entire process of the treatment extremely difficult for the patient. Amidst such scenario, the Indian system of medicine raise hopes through its various systems which can complement the modern system of medicines in better management of cancer and help in improving the quality of life of cancer patients through supportive, prophylactic, palliative and even curative therapies and drugs.

6.1.1 The Ministry of Ayush has submitted multifarious reasons for seeking alternative management for cancer. The increase in burden of cancer along with morbidity also have impact on economy, due to the heavy cost of treatment of cancer through conventional medicine. The cost of treatment, toxicity of the treatment (leading to noncompliance to the treatment which is again a cause for failure in outcomes), failures in the outcomes (due to delayed detection and progressive disease), resistance to the treatment drugs are the challenges posed by the conventional treatment in cancer. Unmet needs of the patients with advanced cancer are associated with their physical symptoms, anxiety, and quality of life. At least one unmet need was reported by 95% (60/63) of the patients. The five highest unmet needs reported by myeloma patients were “need to reduce stress in life”, “need to address concerns of cancer coming back”, “need to handle social/work situations”, “need for emotional support” and “need to move on with life”.

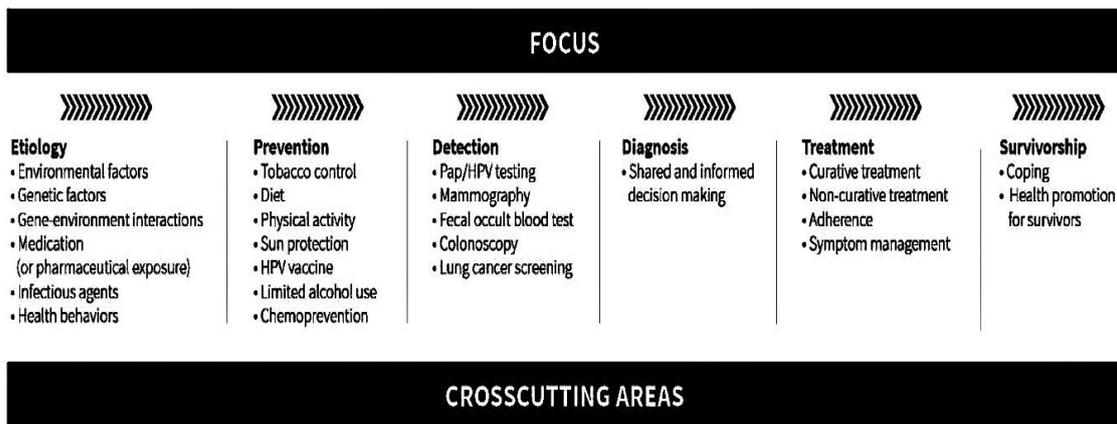
#### **Scope for Ayush/ Ayurveda in Cancer Control Continuum**

6.2 Cancer treatment requires careful consideration of evidence-based options, which can include more than one of the major therapeutic modalities. The selection should be based on evidence of the best existing treatment given the resources available. Cancer can be treated by surgery, chemotherapy, radiation therapy, hormonal therapy, targeted therapy (including immunotherapy such as monoclonal antibody therapy) and synthetic lethality. The choice of therapy depends upon the location and grade of the tumor and the stage of the disease, as well as the general state of the patient (performance status). Many experimental cancer treatments are also under development. Under current estimates, two in five people will have cancer at some point in their lifetime.

6.2.1 The Ministry of Ayush has submitted that Ayurveda has significant role to play at all phases of Cancer care continuum i.e., prevention (screening/ detection/ primary-secondary-tertiary), diagnosis and treatment. Integration of Ayush/ Ayurveda with Conventional management of cancer will have benefits in terms of reducing toxicity, leading to compliance to treatment with a better outcome along with improved quality of life and reduction in expenditures.



## THE CANCER CONTROL CONTINUUM



Adapted from David B. Abrams, Brown University School of Medicine

### Siddha Diagnosis Plan

6.2.2 The Siddha diagnosis for cancer is as per the Siddha system of medicine, it is evident that traditional Siddha diagnostic tool based on Eight tool (*En vagai thervugal*) examination of *Naadi*(Pulse), *Moothiram*(Urine) and *Manikkadai nool* (explained in the Agasthiyar Soodamani Kairu Soothiram) are the diagnostic tools which can be used to assess diagnosis and prognosis in Cancer, besides being safe, cost-effective, and non-invasive.

### Treatment

6.2.3 The drugs must be chosen to enhance bioavailability and also to reduce side effects, to Pacify Agony – Pain management and to improve QoL. *Mezhugu- Rasaganthi mezhugu / Idivallathi mezhugu / Nandhimezhugu* are drugs which have toxicity reports currently

available and they could be the drug of choice. Also as Immunotherapeutic agents drugs like Curcumin / Nellikai / Seenthil are drugs of choices.

6.2.4 Primarily, all the Ayush health care systems deal with the prevention of the health i.e., wellness apart from tackling the sickness. This is the strength of Ayush system of health care which can be utilized in the prevention of many non-communicable diseases including Cancer.

**6.2.5 The Committee notes that Ayush systems can play a significant role at all phases of Cancer care continuum particularly prevention and palliative care. Therefore, the Committee recommends the Ministry to prioritize prevention and palliative care and put in concerted efforts to make Ayush verticals like Ayurveda, Homeopathy and Yoga viable and effective options in these aspects of cancer control continuum.**

6.2.6 Attention of the Committee has been drawn to an article “*Cancer & Ayurveda as a complementary treatment*” Anita Pilmeijer, *International Journal of Complementary & Alternative Medicine* volume 6, issue5-2017 wherein the author has rightly pointed out the following:

*How does Ayurveda aim to treat cancer?*

- i. Curative: Medicines who have shown encouraging results for cancer*
- ii. Supportive: Include Ayurveda in allopathic treatment to combat their side effects and improve quality of life*
- iii. Prophylactic: Include Swasthavritta (Hygiene) Ahar (Diet), Vihara (Life Styles), who are especially required to prevent cancer*
- iv. Palliative: Various groups of drugs to increase immunity Ojas and drugs known for their anti inflammatory properties.*

**6.2.7 The Committee is of the view that not just Ayurveda but all Ayush systems have a role to play in each of these facets i.e. curative, supportive, prophylactic or preventive and palliative cancer care with Ayurveda leading the way. The Committee feels that each of these areas require focused attention especially the curative and supportive aspects for cancer care management by Ayush.**

**6.2.8 The Committee feels that for Ayush systems to make a significant impact in the cancer care continuum, it is essential that all the anti cancer Ayush drugs, therapies and tools must be tested for their efficacy and safety. Even the drugless therapies of Yoga and Naturopathy need to be focused upon for their immense benefits for cancer patients. The Committee believes that the need of the hour is evidence-based Ayush practices and treatments which can complement modern medicine further. It is, therefore, imperative to evaluate traditional practices scientifically and integrating the beneficial practices with the modern medicine.**

### **Existing institutional arrangements for cancer care and management in the AYUSH Sector**

6.3 The Committee is aware that Ministry of Ayush promotes holistic treatment through its Research Councils and national institutes by undertaking various research activities, public health programs such as National Programme for prevention of and control of Cancer,

Diabetes, Cardiovascular Diseases & Strokes (NPCDCS). The Committee has been given to understand by Ministry of Ayush (NCISM) that many Ayurveda teaching hospitals have facility for Cancer Care & Management. Many private practitioners are giving palliative, preventive, curative treatments at different levels to the Cancer patient. It is generally observed that many of the Cancer patients take the help of Ayush treatment for reducing the side effect of chemotherapy as a supplementary treatment etc. Details of Ayush institutions working in the arena of cancer management and treatment is as follows:

### **Ayurveda : Central Council For Research In Ayurvedic Sciences (CCRAS), New Delhi**

6.3.1 CCRAS has its institute Central Ayurveda Research Institute, (CARI) Mumbai with a mandate to conduct Cancer research and which is engaged in clinical and preclinical research in cancer in collaboration with Tata Memorial Centre, Mumbai. Further this institute is also engaged in delivering health care services through Ayurveda and integrative model to the cancer patients. Recently Ministry of Ayush has proposed to develop this institute into 'National Centre of Excellence in the field of Integrative health care and research in Oncology. The other CCRAS institutes, which are engaged in preclinical research viz. [Regional Ayurveda Research Institute \(RARI\), Pune and Central Ayurveda Research Institute \(CARI\), Kolkata do conduct research in cancer.](#)

### **National Institute of Ayurveda (NIA), Jaipur**

6.3.2 National Institute of Ayurveda Jaipur have established Ayurveda Cancer Consultation & Treatment Unit for Cancer Care and Management through Ayurveda.

### **All India Institute of Ayurveda (AIIA), New Delhi**

6.3.3 Center for Integrative Oncology (CIO) has been established as a joint venture of All India Institute of Ayurveda (AIIA), Ministry of Ayush and ICMR-NICPCR, Noida at AIIA, New Delhi. Integrative Cancer Care Unit (ICCU), OPD is running at AIIA. A MoU has been signed between AIIA, IRCH-AIIMS, ICMR-NICPR, NCI-AIIMS, Jhajjar, CCRAS, CCRS for the purpose of integrative cancer care. Under the umbrella of MoU, Center of Ayurveda and Integrative Medicine unit is ready to start at NCI-Jhajjar.

## **HOMOEOPATHY**

6.3.4 According to NCH, treatment to cancer patients is given in OPD/IPD's setup as per requirement of the case. Research studies are taken up by Central Council for Research in Homoeopathy under Ministry of Ayush. Regarding separate oncology centres there is one such center of homoeopathy in Kerala in the district of Thrissur.

## **CCRH**

6.3.5 CCRH has set up Life style disorder clinic/NCD clinic at its 11 institutes/Units wherein routine OPD services are being provided to the cancer patients who seek consultation. These institutes/Units have defined days for providing homoeopathic treatment and integrated health services to patients suffering from cancer. However further steps are required for to strengthen the Cancer Care Plan & Management in AYUSH. An integrated care set-up is in place at All India Institute of Ayurveda, Sarita Vihar, wherein, homoeopathic physician, Ayurvedic physician and Unani physician provide integrated care to cancer patients visiting the institute.

## **NIH**

6.3.6 National Institute of Homoeopathy has been giving special care on cancer patient since many years. A special OPD for cancer patients exist in NIH. In the year 2021-22 total 544 patients were treated including follow-ups.

## **Yoga & Naturopathy : CCRYN**

6.3.7 Council does not have institutional arrangements for cancer care and management. Yoga & Naturopathy are drugless system of medicine. However, Several Research studies on Yoga & Naturopathy have shown beneficial effects in chronic diseases like cancer with respect to reduction of side effects of cancer treatment, psychological stress levels, biochemical parameters & enhancement of QoL and Immune status in cancer patients.

## **NIN, Pune**

6.3.8 NIN, Pune provides ozone therapy, palliative therapies like reflexology, Acupuncture and other external therapies for cancer care. For strengthening cancer care and Management in AYUSH, integrated approach through the non-pharmacological therapies of Naturopathy and Yoga shall be incorporated along with the mainstream medical care. NIN does not have separate oncology centre.

## **Siddha & Unani : CCRS**

6.3.9 Siddha Cancer OPD is provided at SCRUI, Safdarjung Hospital Premises, New Delhi under Central Council for Research in Siddha (CCRS) on every Thursdays, since December 2021 inaugurated as part of the 5<sup>th</sup> Siddha Day. The facilities include free consultation, siddha medicines along with dietary counselling and lifestyle recommendations. Siddha cancer care is also being given at the Integrated Cancer Care Unit at All India Institute of Ayurveda, Sarita vihar, New Delhi on every Friday. CCRS in its out-patient institutes/units regularly conducts Non Communicable disease Out Patient Department and screening programme for cancer.

**6.3.10 The Committee is of the view that the institutional arrangement for treatment as well as management of cancer under Ayush Systems is scattered and is not properly institutionalized. The Committee feels that the Ministry must play a proactive role in ensuring that a policy is framed for delivering cancer care facilities entailing preventive, curative treatments, supportive therapies, palliative care through Ayush institutions. Since Ayurveda possesses potential to lead in cancer care, it can take initiative and frame proper protocols and guidelines for cancer management so that standardized Ayush facilities and care is given to cancer patients for better outcomes.**

**6.3.11 The Committee is given to understand that North-Eastern regions has higher incidence of cancer, thus the Committee expects that a Cancer unit gets operationalised soon in North Eastern Institute of Ayurveda & Homeopathy (NEIAH), Shillong. The Committee believes that Ayush Health and Wellness centres need to be strengthened and upgraded for delivering health facilities to cancer patients. Further, the Committee recommends that Ministry should work towards integrating non-pharmacological therapies of Naturopathy and Yoga with mainstream medical care as this may greatly help in reducing various adverse effects of conventional treatment and go a long way in strengthening cancer care through Ayush.**

**6.3.12 The Committee highlights that with the growing popularity of Ayush systems and the immense faith of the people in these systems, various Ayush institutions must have their own OPD/IPD facilities for catering to cancer patients. At the same time, integrated cancer care set up of Ayush systems must be expanded on the lines of All India Institute of Ayurveda, Sarita Vihar, New Delhi wherein, homoeopathic physician, Ayurvedic physician and Unani physician provide integrated care to cancer patients visiting the institute. Similarly, like in NCI-Jhajjar, Centre of Ayurveda and Integrative Medicine unit should be established in all the 22 AIIMS across the country. The Committee, accordingly, recommends the Ministry to expand the scope of Ayush health facilities in the country and chalk out a plan of action in this regard.**

**6.3.13 The Committee has been given to understand that Ayurvedic medicines have been found to possess potential to halt the progression of cancer. Ayush systems further have the capability of reducing considerably the adverse side effects of conventional cancer treatment through modern medicine. Certain Ayush anti-cancer medicines have been found to be useful in controlling the harmful effects of chemotherapy and radiotherapy and have been successful in helping cancer patients lead a better life. The Committee, accordingly, recommends to the Ministry to further conduct clinical trials for scientifically validating the claims made by Ayush systems in these areas of cancer management and document the positive outcomes. Such efforts will enhance the credibility of these systems. Apart from being crucial in improving the quality of life of cancer patients, it must be ensured by Ministry of Ayush that these medicines are cost effective too.**

#### **Budgetary allocation in AYUSH exclusively for cancer care and research**

6.4 The Committee has been informed by Ministry of Ayush that there is no exclusive budgetary allocation for Cancer care and research in CCRAS. During the last three years, the Council has undertaken research projects in the field of Cancer with a budgetary allocation of Rs.2,45,39,567/-. Cancer care at CARI- medicines are freely distributed and the indoor and panchakarma facilities were also offered at no cost to cancer patients. This expenditure is covered under the RA head of the institute budget. In the National Institute of Ayurveda (NIA), Jaipur, institutional Pharmacy (Ayurveda Rasashala) manufactured the proprietary medicine and continuously supplied to the Cancer Patients through Cancer Unit. Even in All India Institute of Ayurveda (AIIA), New Delhi, there is no such specific fund has been released to AIIA for Cancer Care and Cancer Research.

6.4.1 CCRH too has no separate budget allocation for cancer care. The research on cancer is a funded based on project. However under fundamental research, CCRH is carrying out fundamental research with homoeopathic medicines in cancer models to see the action of the medicines. Similarly, no separate budget has been allocated in Unani Medicine exclusively for cancer care and research on cancer. However, four projects on cancer research has been undertaken by the CCRUM. As for CCRS, there is no separate allocation of budget for cancer. Clinical trials and Preclinical studies are being funded through IMR head. Total budget allocated for conduct of clinical research study to evaluate the clinical safety and efficacy of Siddha drug Nandhi Mezhugu in Stage 1 & 2 Breast Cancer patients (funded by CCRS as part of the IMR project) which is being conducted by Siddha Clinical Research Unit, New Delhi in collaboration with AIIA, New Delhi – Rs. 38,01,800/-. Since August 2021, the fund received for initiation of the study -Rs.13,32,616/-

6.4.2 There is no specific budgetary allocation in AYUSH exclusively for cancer care and research on cancer in CCRYN. There are no separate funds for research in cancer.

**6.4.3 The Committee finds that there is no separate budget for cancer care and research in various Ayush institutes. The Committee is of the view that given the pivotal role played by Ayush systems in management of cancer, focused attention through adequate fund allocation is required for expansion of Ayush cancer care facilities. The Committee, accordingly, recommends that to give impetus to cancer care facilities and research, there should be separate fund allocation for the same. The Committee desires that the Ministry of Ayush should prepare an estimate considering the realistic requirement of its research fund for each research initiative and approach the Ministry of Finance for allocation of adequate research fund.**

#### **Role of AYUSH in prevention as well as early detection of cancer**

6.5 The Ministry of Ayush has submitted that the Union Cabinet on 20th March, 2020 has approved the operationalization of 12500 AYUSH Health & Wellness Centres by upgrading the existing AYUSH Dispensaries and Health Sub-Centres. The guidelines of AYUSH HWCs provide framework for 12 Service delivery areas including Screening, Prevention, Control and Management of Non Communicable Diseases. The objectives of AYUSH HWCs are as follows:

- i. To provide Comprehensive Primary healthcare through AYUSH using team-based approach
- ii. To establish a holistic wellness model based on AYUSH principles and practices focusing on preventive, promotive, curative, rehabilitative healthcare by establishing integration with existing public healthcare system
- iii. To provide informed choice to needy public by making AYUSH services available.

6.5.1 The following activities have been envisaged: Screening, Prevention, Control and Management of Non-communicable Diseases.

Care at Community level through Yoga and Identification of Prakriti of the population for preventive and curative measures.

Support the National Programme through activities such as;

- i. IEC on need for prevention, screening and benefits of early diagnosis.
- ii. Tobacco, Substance use.
- iii. Diet and healthy lifestyle for harmony and health.
- iv. Identification of risk factors, screening and advice.
- v. Watch on compliance.

Care at HWC :

- i. Individualized diagnosis to suggest preventive and curative measures.
- ii. Inclusion of elements of Agni Dipana and Amapachana (to aid proper digestion/assimilation).

- iii. Yoga.
- iv. Diet and lifestyle recommendations for pre-hypertension.
- v. Pre-Diabetes & diabetes.
- vi. Obesity, Lipid disorders.  
Care at referral site:
  - i. All Panchkarma procedures.
  - ii. Diagnosis, treatment and management of complication of hypertension and diabetes diagnosis, treatment and follow up of cancers.
  - iii. Diagnosis and management of occupational diseases such as silicosis, fluorosis and respiratory disorders (COPD and asthma) and epilepsy.
  - iv. Diagnosis and Management of oral cancer.

6.5.2 Implementation of National AYUSH Mission comes under the purview of respective State/UT Governments. Accordingly State/UT Governments may avail financial assistance by submitting the proposal through State Annual Action Plans (SAAPs) as per NAM guidelines. The Ministry of Ayush has also submitted initiatives/efforts of its various institutes in prevention and early detection.

#### **Central Council For Research In Ayurvedic Sciences (CCRAS), New Delhi :-**

6.5.3 For prevention as well as early detection of cancer, CCRAS conducts integrative screening camps/ Programme utilizing Ayush knowledge base and manpower in the National Cancer Control Programme. Awareness and sensitization about the diet, lifestyle and self-care based on prakriti, and season specific Panchakarma procedures are conducted under Ayurveda Cancer Prevention Program (ACPP). People at high risk for cancer, having strong family history of cancer, those with habits of alcohol, tobacco, and other carcinogens may be subjected to the Ayurveda Cancer prevention programme (ACPP). An integrative screening activity of oral health and cancer screening in collaboration with Indian Dental Association (IDA) and CCRAS, Mumbai is in pipeline through central sector scheme on public health of MoA.

#### **National Institute of Ayurveda (NIA), Jaipur :-**

6.5.4 Ayurveda plays a significant part to prevent the Cancer and this is achieved by active campaign to promote the Dinacharya, Ritucharya, Healty Diet etc, active campaign for early detection of cancer through AYUSH personnel. Further cancer prevention can be achieved by Detoxification / Bio purification to the high Risk Patients of Cancer.

#### **All India Institute of Ayurveda (AIIA), New Delhi:-**

6.5.5 At ICCU-AIIA, Cancer Awareness week every year on World cancer day is conducted with series of educative lectures to patients for early detection of different types of cancer. Also, all and suspected individuals of cancer are advised to follow the healthy life style, diet and Yoga based on the Dinacharya (Daily regimen), Rutucharya (Seasonal regimen) and Achara rasayana (Behavioral therapy) concepts of Ayurveda. Further the Panchakarma therapy (Bio-purifactory methods) followed by consumption of Rasayana (rejuvenating)

medicines to maintain the health of healthy individuals and also for prevention of the diseases is also promoted.

### **NIN, Pune**

6.5.6 Towards prevention of cancer life naturally or living in close proximity to nature by adopting healthy life style especially with food habits, practice of Yoga and avoidance of stress could play a major role.

### **CCRUM**

6.5.7 A project entitled “Integration of Unani Medicine with National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS)” was initiated at Lakhimpur Kheri, UP in collaboration between Ministry of AYUSH and Directorate General of Health Services, Ministry of Health and Family welfare. Life Style Clinics were established at District Hospital and 17 CHCs whereas outreach activities were performed by the team at PHC level in the district. The monitoring of the project is done by Central Research Institute of Unani Medicine (CRIUM), Lucknow. The project has created an important spot for itself and has successfully propagated Unani System of Medicine and the role of CCRUM in popularizing the Unani Medicine in the district of Lakhimpur Kheri, Uttar Pradesh. The project was initially approved for three years. Thereafter, the term of the project was extended from time to time and the present extension is up to 30<sup>th</sup> April, 2021. A total number of 5,83,522 patients of NCDs including Cancer have been benefited from the project.

### **NIS & CCRS**

6.5.8 This Institute is periodically conducting Breast Cancer screening programmes and camps in collaboration with Adyar Cancer Institute, Chennai.

6.5.9 Advices to be followed:

Foods like Garlic (*Allium sativum*), Wheat grass (*Thinopyrum intermedium*), Broccoli (*Brassica oleracea* var *italica*), Green tea (*Camellia sinensis*), Soya bean (*Glycine max*), Grapes (*Vitis vinifera*), Peanut (*Arachis hypogaea*), Cashew nuts (*Anacardium occidentale*), Strawberry (*Fragaria ananassa*) Sunflower (*Helianthus annuus*), Avocado (*Persea americana*), Carrot (*Daucus carota* subsp. *sativus*), Orange (*Citrus sinensis*), Lemon (*Citrus limon*), Papaya (*Carica papaya*), Bitter guard (*Momordica charantia*), Tomato (*Solanum lycopersicum*), Pepper (*Piper nigrum*), Leafy vegetables, Nuts and nut butters, Low fat dairy products such as milk, yogurt and cheese, Milk, Egg, Cod liver oil, Fish, Foods rich in fiber, such as whole grains, beans, legumes, Soy bean based products should be taken.

6.5.10 Food to be avoided include- red meat, Pork (*Sus scrofa*), Food that contain high amount of saturated fat, Fast foods, Coffee, Alcoholic beverage consumption, Pickle, Smoked foods, Refined sugars, Micro wave popcorn, Hydrogenated oils, Meat cooked at high temperature, Alcohol consumption, Tobacco.

6.5.11 Siddha kayakarpam for the prevention

1. *Phyllanthus amarus* (*Keezhanelli*):

Whole plant is grounded and prepared as paste mixed with milk/Butter milk. To avoid tamarind and salt - 40 days.

2. *Eclipta prostrata* (Karisaalai)

Whole plant is dried and powdered.

Avoid tamarind & Salt. Taken with tender coconut water 1 month & followed with honey for one month.

3. *Aloe vera* (Kumari)

Fleshy leaf is dried and 1-2 gms to be taken - 40 days.

4. *Zingiber officinale* (Inji): Remove the outer skin

from the rhizome, slice it. Soak in honey 3-5 slice - 40 days

5. *Semecarpus anacardium* (Seerankottai) Nut is prepared as lehyam and 2-4 gm should be taken twice daily. Avoid tamarind and salt - 40 days.

6. *Withania somnifera* (Ammukura): Root is powdered and mixed with 2 ml of ghee - 40 days.

7. *Azadirachta indica* (Vembu): Tender or mature leaf

Is dried & grounded, Ajwain & salt is added.

Avoid Tamarind - 40 days.

8. *Citrus limon* (Elumichai) Fruit juice - 6 Months

9. *Terminalia Chebula* (Kadukkai) Fruit (Epicarp) is made into powder form and taken 500-1000 mg with water in the evening - 40 day.

10. Siddhar Yoga Maruthuvam:

*Arthamachendrasanam, Veerasanam, Sethubandhasanam, Anjaneyasanam, Veerabhadrasanam, Savasanam*

11. SiddharVarmam therapy:

6.5.12 To increase immunity *Porchai, Poigai, Chavvuvarmam*

- i. Siddhar *Pini Anugaa Vidhi*
- ii. Siddhar way of Preventive Measures Against Illness
- iii. Always drink boiled water.
- iv. Take diluted buttermilk and melted ghee
- v. Never eat root tubers except sweet yam
- vi. Never consume food that was prepared in the previous day.
- vii. Always have food after feeling hungry
- viii. Always consume sour curd
- ix. Practice walking after a good diet
- x. Never suppress any natural urges

- xi. Never sleep during daytime
- xii. Take vomiting medication once in six months
- xiii. Take purgative medication every four months in a year
- xiv. Take oil bath twice in a week
- xv. Apply eye medications once in three days
- xvi. Never reside close to dust and articles related to dust

#### 6.5.13 Nutritional Supplements:

- i. *Nellikai and vilvathi Legiyam* – Improves immunity;
- ii. *Ashwaganthi legiyam* and *Amukkara Chooranam*-General debility;
- iii. *Pavala parpam* – Improves immunity;
- iv. *Naga Parpam* – Improves immunity; Blend of Turmeric (known to quench the free radicals)

#### **CCRH**

6.5.14 The Doctors/ Scientists counsel the patients for health promotion, self-examination and need of screening for cancer. Also, the suspected cases based on the complaints, clinical examination and investigations are referred to the oncologist for further evaluation. The role of Ayush physicians in the AYUSH HWCs is early cancer detection based on symptoms and signs, referral and treatment as adjunctive care.

#### **NIH**

6.5.15 Constitutional treatments to prevent cancer in the offspring with genetic history of cancer. Healthy life style, Yoga etc. There is no special technique in Homeopathy for early detection of cancer.

**6.5.16 The Committee strongly believes that Ayush systems of medicine can play a major role in Cancer prevention. The Committee acknowledges various measures like promoting awareness and sensitization about the diet, lifestyle and self-care. The Committee recommends the Ministry to give further impetus to awareness generation on diet and food ideal for consumption and food for avoidance. The Ministry should partner with NGOs and Civil Society Organizations to sensitize school and college students through events like debates and skit. Moreover, information handouts advising people to follow the healthy life style, diet and yoga based on the daily regimen, seasonal regimen and behavioral therapy should be distributed at Public Health Centres (PHCs), Community Health Centres (CHCs).**

**6.5.17 The Committee also recommends the Ministry to organize more integrative screening camps, particularly in rural and remote tribal regions where people should be screened for cancer utilizing Ayush knowledge base. The Ministry should also extensively promote its Ayurveda Cancer prevention programme (ACPP) under which people, at high risk of cancer, having strong family history of cancer, those with habits of alcohol, tobacco, and other carcinogens are specifically targeted and are screened,**

sensitized and made aware about importance of screening and other lifestyle habits to prevent cancer.

**6.5.18 Emphasizing on the potential of Ayush systems to play a major role in prevention of various types of cancers, the Committee recommends the Ministry to explore starting a "Swastha Aahar (Healthy Food)" pakhwada on the lines of Hindi and Swachhata Pakhwada atleast twice a year preferably around International Yoga Day and Gandhi Jayanti. During the mission, people should be encouraged to abstain from consuming packaged food, unhealthy food, extensive outreach and awareness programmes can be planned, essay and quiz competitions around the "Fight Against Cancer" theme can be organized in schools, colleges and housing societies. The Ministry should also find out ways to use social media for disseminating such valuable information to the length and breadth of the country.**

#### **Clinical registry for reporting of cancer cases and its outcome subsequent to treatment by the AYUSH practitioners /hospitals**

6.6 The Ministry of Ayush has submitted that in Central Council for Research in Ayurvedic Sciences (CCRAS), New Delhi, there is no clinical registry for reporting of cancer cases. However, for ensuring comprehensive clinical documentation of cancer patients using Ayurveda treatment as a standalone or add-on therapy based on categorization of patients, CCRAS has developed a format. Further recently CCRAS has launched a portal 'AIFC' (Ayurveda intervention for Cancer) for documentation of cancer case management through Ayurveda which is in its initial phase. It is proposed to upscale this portal in coming days as a Cancer Registry in Ayurveda which will have inter-linkages with other existing registries like Cancer Registry (ICMR) etc. Further a system like National Cancer Grid developed by Tata memorial is also envisaged for Ayurveda and integrative oncology. As per National Institute of Ayurveda (NIA), Jaipur, the institutional Ayurveda Cancer Consultation & Treatment Unit, maintain the record of Cancer patients. A Network For Ayush Cancer Care (NFACC) is functioning under CIO-AIIA where the practitioners are sharing their clinical experiences of treating different cancerous conditions.

6.6.1 As regards Siddha, a separate clinical OPD is functioning at the Siddha Clinical Research Unit, Safdarjung Hospital Premises, New Delhi. Currently there is no cancer clinical registry, however, steps for registering at the State Cancer registry will be initiated. The cancer patients presently are being registered in the Ayush Hospital Management Information system (AHMIS) portal where the history, lab investigations and drug regimen are being maintained. The case files of each patient w.r.t case details and Drug management are being documented. Interesting Case studies documented at the Unit OPD and Integrative cancer care, AIIA are being prepared as manuscripts for publication at reputed indexed journals.

6.6.2 There is no clinical registry for reporting of cancer cases being treated by homoeopathy but clinical research trials (including cancer) are being registered on Clinical Trial Registry of India which is mandatory for such trials. In CCRH, there is no clinical registry for reporting of cancer cases and its outcome subsequent to treatment by the AYUSH practitioners /hospitals. NIH, Kolkata had made correspondence with ICMR-National Centre for Disease Informatics And Research, Department of Health Research, Ministry of Health and Family Welfare, Government of India in the year 2019 to set up Cancer Registry in NIH, Kolkata. However, it was not successful because NIH could not meet the prerequisite criteria like

presence of Surgical and Medical Oncology department, Department of Pathology with active histopathology activities etc.

**6.6.3 The Committee believes that cancer registries are very important as they collect accurate and complete cancer data that can be used for cancer control and epidemiological research, public health program planning, and patient care improvement, and finally all of these activities reduce the burden of cancer. The Committee is in agreement that comprehensive clinical documentation of cancer patients using Ayurveda, Homeopathy and Siddha treatment as a standalone or add-on therapy should be done. Ayush specific cancer registries can help in understanding the efficacy of these treatment methods which would grant these alternative forms of treatments much needed legitimacy. Therefore, the Committee, recommends the Ministry to put concerted efforts to operationalize the Portal/ Cancer Registry in Ayurveda and other Ayush systems and ensure that these registries have inter-linkages with other existing registries like Cancer Registry of ICMR.**

**6.6.4 The Committee would also like to be apprised of the experiences/feedback shared on the Network for Ayush Cancer Care (NFACC) under AIIA regarding clinical experiences of treating different cancerous conditions and whether the information so shared has been put to good use in evaluating the data for formulating cancer treatment protocol and guidelines. The Committee further recommends the Ministry to engage State Governments for initiating State Cancer Registry in their own States.**

### **Improving Quality of life of cancer patients through AYUSH systems**

6.7 The Committee has been given to understand by the Ministry that increasingly, cancer is managed in a multidisciplinary team setting to improve outcome and decrease morbidity of treatment. In most cases, concurrent use of palliative care services and active anti-cancer therapy are necessary to maintain quality of life. The palliative care should be good for the patient and families and at the same time must be cost effective to the patient and health system by continuing to function normally, having less hospital admissions, causing less burden on community support systems.

6.7.1 Palliative care, which focuses on improving the quality of life of patients and their families, is an essential component of cancer care. Accelerated action is needed to improve cancer care, achieve global targets to reduce deaths from cancer and provide health care for all consistent with universal health coverage

#### **Awareness**

6.7.2 Awareness about Causative factors / Virulence will help in Prevention, and particularly primary prevention, seems an effective way which may reduce at least 10-12 percent of cases turning to secondary prevention. Prevention strategies are cheaper, covers whole population including the kith and kin of high risk category. Various levels of awareness is required such as awareness among adolescents and teens in Schools /awareness about vaccines and prevention of Cancer. Awareness should also be increased on passive smoking / active smoking as leading causes of Cancer. Furthermore, stage shows/ road shows/ social media Handles should be used to spread about Tobacco related side effects.

#### **Screening**

6.7.3 Screening is also complemented by awareness as many cases who self-check and got diagnosed in early stage were capable of getting a proper care and cure. Awareness and

Screening are the tools to intervene population as a whole to understand and pick up the Geoclimatic patterns of Cancer. System specific and Environmental specific Prevention strategies should be taken into account.

## **Research**

6.7.4 Research is the mainstay of the centre and focus areas will be laboratory, experimental and clinical studies. Efforts will also be made to study the herbal, mineral & herbo-mineral drug for its anticancer effect & efficacy in various combination. Drug development program will also be initiated by scientific way to prove the anticancer effect & efficacy of Ayurveda drugs.

**6.7.5 The Committee is of the firm view that Ayush systems can have significant impact in improving the quality of life of cancer patients through its various therapies and palliative care services. It is felt that a multi-disciplinary approach may go a long way in cancer care continuum which is cost effective and help in alleviating the various side effects of cancer treatment.**

**6.7.6 The Committee feels that drug development program is an important area which needs to be focused upon. All out efforts must be made to study the herbal, mineral & herbo-mineral drug for its anticancer effect & efficacy in various combination. The Committee would like the Ministry to ensure that all such cancer screening, detection and other care by Ayush systems are properly documented.**

### **Integrative Oncology: Integration of allopathic as well as AYUSH systems for cancer care and management**

6.8 The Committee has been given to understand that many Ayush practitioners are practicing Integrative Ayurveda Oncology models and have successfully managed cancer symptoms. CCRAS has documented the clinical case diaries and sheets of Dr. C.P. Mathew and the analysis is currently ongoing with respect to managing cancer patients very well. It has also been submitted that in view of ensuring comprehensive clinical documentation of cancer patients using Ayurveda treatment as a standalone or add-on therapy based on categorization of patients, CCRAS has developed a format and recently launched a portal 'AIFC' for documentation of cancer case management through Ayurveda to make data base and evidence base. This data base further may be explored for the potential leads that can be used further in integrative oncology setups and clinical research projects.

6.8.1 The Committee also has been apprised that currently few institutes like ICTRC, Pune is engaged in integrative oncology and CCRAS institute is engaged in clinical and basic research in cancer in collaboration with Tata Memorial Centre. All India Institute of Ayurveda has a set up of Integrative oncology which has all Ayush systems under one roof for cancer management. Tata Memorial Centre is coming up with new Integrated Centre for Treatment Research and Education in Cancer near to Mumbai and Ministry of Ayush, CCRAS is committed to support this project. Integrative management in real clinical set up is much needed than merely collocation of the multisystem under one roof.

**6.8.2 The Committee commends the Ministry of Ayush for its initiatives on integration of allopathic as well as Ayush systems for cancer care and management. The Committee recommends the Ministry to develop a detailed format for uniform and comprehensive documentation of cancer patients using Ayurveda treatment as a standalone or add-on**

**therapy, the Committee is of the opinion that the database generated may be used for exploring ways to further improve the integration of allopathic as well as Ayush systems. The Committee recommends the Ministry to put concerted efforts in setting up integrative oncology centres in addition to collocation of Ayush multi systems under one roof.**

6.9 Various Ayush Institutes have also submitted about initiatives and efforts being made on their part for integrative oncology.

### **Central Council For Research In Ayurvedic Sciences (CCRAS), New Delhi**

6.9.1 The functional integration of Allopathy and Ayurveda is being forged at research and care level in cancer. However, it is felt that drug, drug interaction issues and inhibition of oncologists towards integrating Ayurveda intervention with Cancer care poses a challenge. Though efforts are being made to investigate the drug-drug interaction with chemotherapeutic agents however there is a limitation as Ayurveda interventions are not only drug based but also include therapies, dietary & lifestyle interventions.

6.9.2 CCRAS is in the endeavor of research in collaboration with reputed cancer institutes like TMC, AIIMS New Delhi, and DRDO in cancer.

- i. CCRAS institute in Mumbai is also engaged in integrative cancer care and similarly such services are offered at some other institutes/ centres across India however this model is in infancy.
- ii. CCRAS and its Mumbai institute is closely working with Tata Memorial Centre through a MoU between two Institutes and initiatives like Joint clinics, Joint working groups has been recently started.
- iii. CARI has received land from CPWD in Bhandup East, Mumbai and Ministry of Ayush is proposing to upgrade this institute as 'National Centre of Excellence in the field of Integrative health care and research in Oncology'.

6.9.3 The model of functional integration in cancer is in initial stage but its evolving and TMC is also coming up with a new set up of Integrative Centre for Treatment, Research and Education in Cancer (ICTREC) with technical support of Ministry of Ayush. This is an indicator that the integration of systems for cancer care and management hold a lot of potential.

### **Institute of Teaching & Research in Ayurveda (ITRA), Jamnagar**

6.9.4 As per the data and research available in the institute, Ayurveda helps to combat side effects of radio therapy and chemo therapy and helps to complete the cycles of chemo/radio therapy.

### **All India Institute of Ayurveda (AIIA), New Delhi**

6.9.5 There is positive response from the conventional medical system with some hindrance in accepting oral medications from Ayush system of medicines in terms of safety and drug interactions. Many studies have reported that Ayurvedic treatment is one of the most commonly used treatments in patients with cancer in India. Most patients using Complementary and Alternative Medicine (CAM) reported satisfaction with the treatment. It is observed that patients with cancer have a tendency of polypharmacy, coadministration of drugs of multisystem unnoticed to the treating Oncologist. Hence, the Ministry believes that

there is a need to integrate AYUSH with the modern system of medicine to harness its potential benefits.

### **Yoga & Naturopathy Section (CCRYN)**

6.9.6 Several Allopathic institutions are integrating Yoga interventions in cancer patients. There are level 1 Evidence for use of yoga in management of fatigue, chemotherapy induced nausea and emesis, quality of life and reduction in anxiety, depression and distress in cancer patients undergoing conventional treatment. These are reflected in National Cancer Care Network Guidelines, USA and American Society of Clinical Oncology Guidelines, USA

### **NIN, Pune**

6.9.7 As far as the ozone therapies provided at NIN is concerned for certain cancer conditions the prognosis was found encouraging.

### **CCRUM**

6.9.8 A project entitled “Integration of Unani Medicine with National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS)” was initiated at Lakhimpur Kheri, UP in collaboration between Ministry of AYUSH and Directorate General of Health Services, Ministry of Health and Family welfare. Life Style Clinics were established at District Hospital and 17 CHCs whereas outreach activities were performed by the team at PHC level in the district. The monitoring of the project is done by Central Research Institute of Unani Medicine (CRIUM), Lucknow. The project has created an important spot for itself and has successfully propagated Unani System of Medicine and the role of CCRUM in popularizing the Unani Medicine in the district of Lakhimpur Kheri, Uttar Pradesh. The project was initially approved for three years. Thereafter, the term of the project was extended from time to time and the present extension is up to 30<sup>th</sup> April, 2021. A total number of 5,83,522 patients of NCDs including Cancer have been benefited from the project.

### **CCRS**

6.9.9 Integration of Ayush has given scope for patients who enter the institutes for Primary cancer care, Also as Immuno therapeutics in Cancer care and Supportive therapy in Side effect prevention. Siddha medicine as part of the integrated therapy module is found to be supportive in reducing the ill effects of radio and chemotherapy. Also, it reduces the clinical symptoms of the patients as well improving the overall health status.

### **CCRH**

6.9.10 CCRH has undertaken few studies with adjunctive homoeopathy for treating side effects of breast cancer due to chemotherapy /radiotherapy, oral mucositis, and tautopathic drugs for cancer treatment. The OPD experiences on add on homoeopathy in managing different symptoms in cancer management with adjunctive homoeopathy have encouraging results.

### **NIH**

6.9.11 The integration of allopathic as well as AYUSH systems for cancer care and management will be highly beneficial for the patients. There are patients who have been receiving homoeopathic treatment after surgery/ chemotherapy with good results.

**6.9.12 The Committee is of the view that collaboration with reputed cancer institutes like TMC, AIIMS, New Delhi, and DRDO in cancer research and treatment is a step in the right direction. The Committee believes that such collaborations must be expanded and integrative cancer care services must be made available for cancer patients throughout the country. A National Centre of Excellence in the field of Integrative health care and research in Oncology by upgrading CARI is a wonderful initiative by the Ministry of Ayush which necessitates proper monitoring of the project so that this National Centre of Excellence is started as early as possible.**

**6.9.13 Attention of the Committee has been drawn to the drug-drug interaction issues with chemotherapeutic agents. The Committee believes that this is an area of concern and require further investigation and research. The Committee, accordingly, recommends the Ministry to prioritize this area of concern and focus on studies on this issue for clearing the doubts and inhibitions of oncologists regarding the drug-drug interaction and efficacy of treatment.**

**6.9.14 The Committee notes that several allopathic institutions are integrating Yoga interventions in cancer patients. Considering the efficacy of yoga in management of fatigue, chemotherapy induced nausea and emesis, improvement in quality of life and reduction in anxiety, depression and distress in cancer patients undergoing conventional treatment, the Committee recommends the Ministry to work towards getting yoga included in oncology guidelines for treatment of Cancer.**

**6.9.15 The Committee takes note of the project entitled “Integration of Unani Medicine with National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS)” which was initiated at Lakhimpur Kheri, UP. The Committee would like to be apprised about the performance and current status of life style clinics that were established under this project at District Hospital CHCs. Considering that the project was successful in propagating Unani System of Medicine, the Committee recommends that the project must be continued further and similar projects should be started in other districts of the country.**

#### **NAM**

6.9.16 Ministry of Ayush has submitted that integration of AYUSH with National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS), a pilot project of AYUSH was successfully run from 2016 in collaboration with Directorate General of Health Services (DGHS), Ministry of Health & Family Welfare, Government of India in 6 districts i.e. Bhilwara (Rajasthan), Surendranagar (Gujarat), Gaya (Bihar), Krishna (Andhra Pradesh), Darjeeling (West Bengal) and Lakhimpur kheri (Uttar Pradesh) of the country through Research Councils of Ministry of Ayush. The evaluation of this project brought out the importance of AYUSH in supporting the control of Non Communicable Diseases (NCDs) in the implementing districts. Accordingly, NPCDCS has been continued in a program mode under the National AYUSH Mission (NAM) in the same 6 States where this programme was running in a pilot mode. The AYUSH HWCs being operationalized under the Mission will be converged with this program so that primary screening at the grass root level will be co-ordinated through AYUSH HWCs as per availability. The referral services will be catered by the AYUSH units at District and Community Health Centre (CHC) NCD cells.

6.9.17 This program will be implemented in coordination with Ministry of Health & Family Welfare by establishing AYUSH units at District NCD Centres, Community Health Centres

and also making alignment with PHCs for outreach activities in six States i.e. Andhra Pradesh, Bihar, Gujarat, Rajasthan, Uttar Pradesh and West Bengal where this programme is already implemented in pilot mode.

6.9.18 Implementation of National AYUSH Mission comes under the purview of respective State/UT Governments. Accordingly State/UT Governments may avail financial assistance by submitting the proposal through State Annual Action Plans (SAAPs) as per NAM guidelines.

**6.9.19 The Committee has been given to understand that the AYUSH HWCs being operationalized under the National Ayush Mission will be converged with the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) so that primary screening at the grass root level will be co-ordinated through AYUSH HWCs as per availability. The referral services will be catered by the AYUSH units at District and Community Health Centre (CHC) NCD cells. The Committee appreciates this step of both the Ministry of Health & Family Welfare and Ministry of Ayush and is of the view that this facility of primary screening at Ayush HWCs and referral services by Ayush units at district and CHC level must be expanded in all the States. The Committee also recommends the Ministry to engage and sensitize State Governments to avail financial assistance under NAM for cancer screening at HWCs and referral services and send their State Annual Action Plans accordingly.**

6.9.20 The Committee feels that the Indian systems of medicine should be used appropriately in management of cancer. The various limitations in access to quality and affordable cancer care can be addressed through utilizing both the modern as well as Ayush systems. The need of the hour is to integrate both modern and Ayush systems of medicine so that cancer care is better managed in the interest of the cancer patients. Therefore, the Committee recommends the Ministry to work towards integrating Ayush with the modern system of medicine to harness its potential benefits. The Committee believes that the patients should have the option for going for conventional treatment or a combination of both modern medicine as well as Ayush systems for better outcomes. Extensive basic and clinical research in cancer should be conducted by Ayush institutions in collaboration with institutes like AIIMS and Tata Memorial Centre to generate evidence of the benefits of Ayush interventions through rigorous clinical documentation and well-conducted studies so as to develop the integrated approach for cancer treatment. The Committee recommends that Ayush knowledge and manpower should be utilized in prevention and screening camps organized under National Cancer Control Programme.

### **Integrative Oncology at TMH**

6.10 Tata Memorial Hospital is planning to establish itself as an integrated cancer hospital with a mission to provide leadership for advancing integrative AYUSH approaches through service, education and research for enhancing cancer control and cure. The mandate of the center is as follows:-

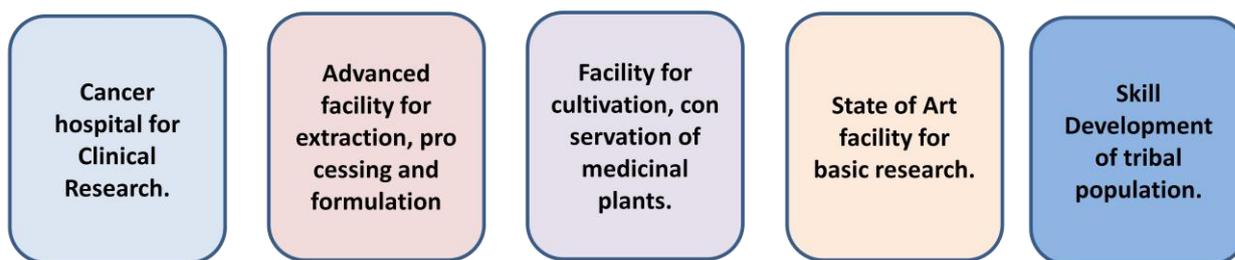
- i. Cultivation and conservation of country's medicinal plants with potential benefits in cancer care.
- ii. To create a platform for interaction of all stakeholders involved in service, education, and research in AYUSH.

- iii. To assist the AYUSH ministry in the evaluation and monitoring of related guidelines, policies .and legislation.
- iv. To create evidence for integration of AYUSH into standard protocols of cancer care.
- v. To establish a publicly available library of various AYUSH modalities having a beneficial role in cancer prevention, treatment, or recovery. \

6.10.1 TMH has the approval for the creation of an Ayurvedic hospital with an applied research facility. The aim of this facility is to create a platform for engaging every relevant stakeholder to partner in promoting traditional Indian medicine. They have also received a letter of support from several reputed institutes in this area such as Central Ayurveda Clinical Research Institute for Cancer (CARIC) is being planned under the AYUSH Department, Indian Institute of Integrative Medicine, Council of Scientific & Industrial Research, Jammu, Agharkar Research Institute, Pune & Dev Sanskriti Vishwa Vidyalaya, Haridwar.

### 6.10.2 Evaluation of AYUSH Products at Advanced Centre for Treatment, Research & Education in Cancer (ACTREC), TMC

No	Ayush Product	Study	End Point	Cancer Type	Outcome
1	Carctol-S	Prospective phase II trial	1. Efficacy 2. Toxicity 3. Immunomodulatory effect	High grade serous epithelial ovarian cancer at first serological relapse	Carctol-S treatment of Ovarian Cancer patients may help in enhancing Immune effector activity and elimination of immuno suppressive mediators
2	Carctol-S	Carctol S as a formulation	Anti-cancer activity	Ovarian Cancer	Synergistic action with cisplatin against growth of ovarian cancer cell lines.  In mice model of cervical cancer, Carctol-S treatment resulted in 85% tumor reduction
3	CARAF & CAGHE	In vitro cytotoxicity assays	1. Immunomodulatory 2. Anti-cancer Activity	Pre-clinical models of Leukemia, Lymphoma, Melanoma, Lung and Breast cancer	CARAF reduced cell growth of various cancer cell lines viz. K562 (leukemia), MCF-7 (Breast ca), MDA-MB-231 (TNBC), B16F10 (melanoma)



## Indigenous Medicinal Plant Research Facility

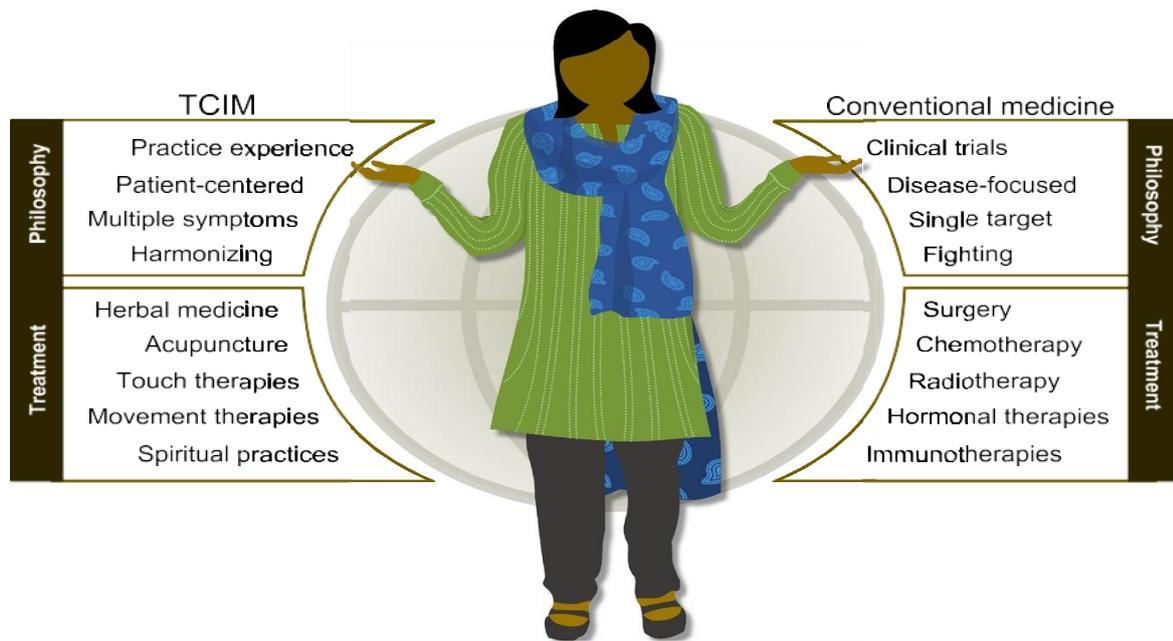


**6.10.3 The Committee appreciates the integrated cancer care being provided by TMH in providing leadership for advancing integrative Ayush approaches through its various efforts be it creating evidence for integration of Ayush into standard protocols of cancer care, assisting Ayush Ministry in evaluation and monitoring of related guidelines, policies and legislation, cultivation and conservation of medicinal plants and its potential benefits in cancer care etc. An indigenous medicinal plant research facility for cultivation and conservation of such plants along with skill development of tribal population for research is a novel initiative for recognizing the immense potential of medicinal plants for cancer treatment.**

**6.10.4 The Committee also appreciates the evaluation of Ayush drugs by Advanced Centre for Treatment, Research & Education in Cancer (ACTREC), TMC. Such evaluation and scientific studies will bring out credible results which will go a long way in furthering the integrative oncology. This will also ensure efficacy and safety of Ayush drugs like carcitol for its anti-cancer properties. The Committee recommends to the Ministry to promote such evaluation studies of all Ayush drugs so as to provide scientific backing to efficacy of Ayush drugs.**

6.10.5 Attention of the Committee has been drawn to an article *Integrative oncology: Addressing the global challenges of cancer prevention and treatment by JunJ.Mao etal (in CA :A Cancer Journal for Clinicians Volume 72,Number2, March/April 2022)* wherein it has been pointed out that in many low and middle income countries, traditional, complimentary and integrative medicine (TCIM) practices are deeply rooted in societal cultures and traditions and have the capability to manage various types of cancers. However, there have been tension between the two which necessitate the integration of both the systems for better management. Key differences between conventional cancer care and TCIM perspectives hinder collaboration and integration. Conventional medicine uses a bottom-up, micro-to-macro approach to understand health and disease, examining how structure leads to function. On the other hand, TCIM embraces a top-down, macro-to- micro approach, examining how function necessitates structure. Conventional medicine and TCIM have distinct philosophies and treatment approaches. The conventional oncology paradigm focuses on treating cancer as a biologic disease with identifiable mutations and targets. Treatments have clear, basic

science mechanisms and are evaluated through rigorous clinical trials with well defined end points. As a result, modern anticancer approaches such as surgery, chemotherapy, radiation, hormonal treatment, targeted therapy, and immunotherapy have increased survival for many types of cancer. TCIM, instead, often relies on ancient theory and wisdom as well as thousands of years of empirical practice with people of a particular culture and community. The treatment focuses on the person with the illness rather than the disease itself and embraces the holistic nature of health as the interplay among body, mind, and spirit. The therapeutic approaches, including herbs, acupuncture, touch therapies, and spiritual practices, achieve harmony in the patient regardless of disease status.



**FIGURE. Tensions Between Traditional, Complementary, and Integrative Medicine (TCIM) and Conventional Medicine in Low-and Middle-Income Countries**(*Integrative oncology: Addressing the global challenges of cancer prevention and treatment by JunJ.Mao etal (in CA :A Cancer Journal for Clinicians Volume 72,Number2, March/April 2022)*)

**6.10.6** The Committee takes into account that modern anticancer approaches such as surgery, chemotherapy, radiation, hormonal treatment, targeted therapy, and immunotherapy have increased survival for many types of cancer, on the contrary traditional methods often relies on ancient theory and wisdom as well as thousands of years of empirical practice with people of a particular culture and community. The treatment focuses on the person with the illness rather than the disease itself and embraces the holistic nature of health as the interplay among body, mind, and spirit. The Committee, therefore, strongly recommends that Ministry of Ayush and Ministry of Health and Family Welfare to chalk out Action Plan to promote integrative Oncology having the best elements of both the systems of medicine.

**6.10.7** The Committee finds the philosophy and treatment of both the modern/conventional and the traditional system of medicine quite interesting and is of view that given the popularity of Ayush systems in the country , it would be much better to integrate and collaborate both the systems for the benefit of the cancer patients. Whatever the reasons maybe for the patients opting for one of two systems or both the

systems together, it is high time to put in place a policy for integration of both the systems in management of cancer. The Committee believes that Ministry of Health and Family Welfare and Ministry of Ayush must work towards an integrative oncology policy and lay down guidelines for such treatment protocols and required health infrastructure for the same. Example of TMH evolving an integrative cancer care approach by including Ayush must be replicated by other premier cancer institutes for the benefit of cancer patients.

### **Cancer Research in AYUSH**

6.11 The Ministry of Ayush has submitted details of Projects & research studies which have been done to ascertain the efficacy and safety of AYUSH drugs in management of cancer.

#### **Evidences for Ayush in Cancer care and control**

6.11.1 The published literature on the Ayush herbs/interventions as standalone and add on to conventional treatment in various conditions of cancer as treatment and prevention including preclinical data has some promising leads.

#### **State of research in Ayush in cancer**

6.11.2 CCRAS in collaboration with Tata Memorial Centre and various centres is conducting research in preclinical and clinical area. (list of ongoing studies at CCRAS and TMC enclosed Annexure- II). Further a glance at Clinical Trial Registry of ICMR shows that many studies are registered by other institutes engaged in integrative oncology.

#### **Research Methodology in Integrative Ayurveda Oncology**

6.11.3 Single plants/ herbs extracts and pure molecules are explored for various conditions in cancer which is a reductionist approach. Ayurveda and other Ayush systems generally follow wholistic approach towards the wellness and illness. There is a huge potential in Ayurveda principles and fundamentals for the exploration in cancer at various levels i.e., prevention, management and rehabilitation using the modalities like Panchakarma, Rasayana, Diet and nutrition. Ayurveda as a whole system approach should be explored in the various conditions and stages of cancer. AMRA study is one example where it was elicited that the whole system approach of wholistic science can be explored in clinical research setting.

#### **Central Council for Research in Ayurvedic Sciences (CCRAS), New Delhi**

6.11.4 Cancer related research are as under:-

- i. A phase II trial to study of efficacy, toxicity and immunomodulatory effect of Carctol-S in high grade serous epithelial ovarian cancer at first serological relapse in collaboration with Tata Memorial Hospital (TMH) and ACTREC
- ii. Assessment of Prakriti (Ayurvedic body constitution) of patients with Cervical and Ovarian cancers.
- iii. Understanding the mechanistic role of CARAF and CAGHE as immunomodulatory and anti-cancer compounds against preclinical models of leukemia, lymphoma, myeloma, lung, and breast cancer.

- iv. Understanding mechanistic role of Carctol-S as an immunomodulatory and anti-cancer formulation against ovarian cancer.
- v. Ayurveda Interventions for Cancer: Systematic Review, Meta-analysis; and Revival, Documentation, Validation, and analysis of data from practitioners, institutes

6.11.5 CCRAS is in the endeavor of evidence generation for cancer management through research at various levels. Screening of medicinal plants for their anticancer activity has also been conducted at ACTREC (TMC) Mumbai and at Regional Ayurveda Research Institute, (CCRAS) Pune. Study of topical application of Ayurveda interventions for wound healing in gamma-radiation-induced skin wound model has been carried out in collaboration with INMAS, (DRDO) and further its clinical study is in pipeline with TMC. Mechanistic studies of Ayurveda formulations as immune modulatory and anti-cancer activity in preclinical models of different type of cancer are ongoing in collaboration with Tata Memorial Centre, Mumbai. Evaluation of cytotoxicity, pharmacokinetics, anti-cancer activity, detailed molecular mechanism of Ayurveda intervention in vitro and in vivo anti-tumor xenograft models in collaboration with CSIR-Indian Institute of Chemical Biology (IICB) Kolkata is being carried out.

6.11.6 The Council has developed an Ayurveda formulation AYUSH QOL2C in improving quality of life in Cancer through a systematic process of drug development viz. drug standardization, preclinical safety/toxicity studies and clinical studies in collaboration with AIIMS New Delhi etc. A clinical research project of Carctol S (a formulation under drug development by CCRAS) in high grade serous epithelial ovarian cancer at first serological relapse in collaboration with Tata Memorial Hospital (TMH) and ACTREC is ongoing. Study of Association of Prakriti (Ayurvedic body constitution) with Cervical and Ovarian cancers in collaboration with Tata Memorial Hospital (TMH), Mumbai is also being conducted. A research project on Ayurveda Interventions for Cancer: Systematic Review, Meta-analysis; and Revival, Documentation, Validation, and analysis of data from practitioners, institutes is also ongoing at CCRAS institute in Mumbai. – under this project data from various practitioners is getting collected and the analysis of this will generate leads for further its validation through appropriated clinical studies. Review of the published data on Ayurveda interventions for cancer is also done and published in the peer reviewed journal.

#### **Institute of Teaching & Research in Ayurveda (ITRA), Jamnagar**

6.11.7 Many clinical research works have been carried out in the ITRA few examples are:

- i. “Efficacy of Rasayana Avaleha as adjuvant to radiotherapy and chemotherapy in reducing adverse effects”.
- ii. Combating the Toxicities of Chemotherapy with Rasayana: A Step Towards Integrated Oncology.

Other than research works, seminar and workshops have also been organized in the campus in the past.

#### **National Institute of Ayurveda (NIA), Jaipur**

6.11.8 Project Under Process with Tata Cancer Centre Mumbai & Aimil Pharma

- a) Evaluation of mechanistic role of V2S2 as palliative and anti-cancer compound against pre-clinical models of Breast, Oral, Pancreatic, Cervical, and Colon cancer.

- b) Anti-Cancer Palliative Effect of V2S2 & IB (Ayurvedic Compound) in 3<sup>rd</sup> & 4<sup>th</sup> Stage of Cancer Patients: An Open Labeled Clinical Control Study

#### 6.11.9 Research Paper related to Cancer Prevention & Ayurvedic Management

- a) Ayurvedic Aspect of Endometrial Carcinoma and Its Ayurvedic Management. IJRAP 7/1, Jan-Feb 2016; DOI: [10.7897/2277-4343.0714IF-6.33](https://doi.org/10.7897/2277-4343.0714IF-6.33) (Review)
- b) *In vivo* anticancer activity and toxicity of Ayurveda compound W.S.R. to leukemia. Journal of Indian System of Medicine, (7 / 1) January-March 2019; DOI: 10.4103/JISM.JISM\_2\_19. (Primary Research)
- c) Role of Ayurveda in Management of Leukemia (Raktarbuda). IJPSR 01 February,2016;;DOI: 10.13040/IJPSR.0975-8232.7(2).520-30IF 1.230 (Review)
- d) Anticancer Activity and Cytotoxicity of Moringa Oleifera and Calotropis Procera: An In Vitro Study. IJRAR October 2020, Volume 7, Issue 4. Impact factor: 5.75(Primary Research)
- e) Role of Ayurvedic Diet in Patients of Gall Bladder Cancer. Int J Ayu Pharm Chem 2020 (12/ 1)(Review)
- f) In Vitro Evaluation of Anticancer Activity of Herbal Extract V2S2 ( Coded Drug) On Various Human Cancer Cell Lines- Accepted for Publication in South Asian Journal of Cancer. (Primary Research)
- g) Ayurvedic Method of Diagnosis and Management of Cancer: A Clinical Experienced Based Protocol - Journal of Research in Indian Medicine 2022.
- h) Clinical effect of Ayurveda medicine in recurrent post-operative ovary carcinoma: a case report- TMR Integrative Medicine 2022

#### **All India Institute of Ayurveda (AIIA), New Delhi**

6.11.10 Many preclinical studies have been conducted on Ayush system of medicines to prove safety and also few clinical researches are also published to evidence the safety and efficacy of certain medicines

**6.11.11 The Committee observes that there is huge potential in Ayurveda for management of cancer at various levels particularly in prevention and rehabilitation. The Committee, therefore, recommends that effect and impact of Ayurveda as a whole system should be explored in the various conditions and stages of cancer. The Committee notes that Ayurveda management versus Methotrexate in Rheumatoid Arthritis (AMRA) study has shown that whole system approach of holistic science can be explored in clinical research setting. The Committee further recommends that Ministry should embark upon to replicate AMRA study and its findings in cancer care and management.**

**6.11.12 The Committee acknowledges the research work being carried out by ITRA, Jamnagar. The Committee would like to be apprised about the findings of these two clinical research studies. The Committee recommends the Ministry to identify more areas for research and allocate more funds for clinical studies. The Committee also recommends the Ministry to identify ways for incorporation of the findings of clinical research studies in the prevention, treatment and palliative care methods.**

## CCRUM

6.11.13 Following are the studies by CCRUM:

- i. Evaluation of Aftimoon (*Cuscuta Reflexa* Roxb.) Plant and its Seeds on Different Human Cancer (Sartan) Cell Lines.
- ii. Delineating the anti-cancer potential and the mechanism of action of Unani medicinal formulation *Itrifal-e-Aftimoon* in Chronic Myelogenous Leukemia.
- iii. Phytochemical standardization and evaluation of anti-cancer and immunomodulatory activity of Unani formulation, *Itrifal ghudadi*.
- iv. Evaluation of the Anticancer Potential of a Unani Pharmacopoeial Formulation, 'Dawa-UI-Kurkum'.

## CCRS

6.11.14 Central Council for Research in Siddha (CCRS) has undertaken research in including Cancer through IMR projects. Details of which are:-

- i. Clinical trial to evaluate the safety and efficacy of Siddha Medicine Nandhi Mezhugu in Stage I and II Breast Cancer Patients.
- ii. Total Budget allocated for conduct of clinical research study to evaluate the clinical safety and efficacy of Siddha drug Nandhi Mezhugu in Stage 1 & 2 Breast Cancer patients (funded by CCRS as part of the IMR project) which is being conducted by Siddha Clinical Research Unit, New Delhi in collaboration with AIIA, New Delhi.
- iii. CTRI Registration completed , IEC Clearance obtained Medicines purchase, Screening of Patients, Investigations – Under process
- iv. Preclinical animal studies evaluating the safety and efficacy of Nandhi mezhugu (On mammalian tumour cells) have already been completed as part of the collaborative project between SCRI (CCRS), Chennai and TANUVAS.
- v. Following the above justification, Siddha Drug Nandhi Mezhugu will be given as standalone therapy. This siddha Herbo metallomineral drug is evaluated for the Phase II trial Pilot Phase Clinical trial in the Breast cancer patients.
- vi. Development of Siddha Treatment Guidelines for non – communicable diseases

6.11.15 Other research activities related to cancer :

- Side effects of cancer therapy are one of the most important issues faced by cancer patients during their illness. The importance of Pharmacovigilance in oncology must be highlighted with every effort, to improve safety and offer cancer patients every possible help to improve their quality of life during such a critical period of their lives. Pharmacovigilance in oncology helps to prevent, detect and manage drug-induced adverse reactions; it also helps to prevent avoidable medical prescription orders.
- Conduction of Science Club Meeting monthly (Online) Cancer related topics will be focused.

- A book on the Collective Cancer formulations as found in the Classic Siddha Textbooks is initiated as part of the Cancer Literary research.
- Steps are being taken for initiation of an effective and affordable Siddha Cancer Formulation for Patent Application.
- A virtual conference (Webinar) may be conducted based on the new strategies and action care plan for the treatment of Cancer through Integrative Siddha Medicine
- Siddha Integrative Palliative Care Therapy is planned in Siddha Unit (CCRS) New Delhi, along with the Cancer Dept of Safdarjung Hospital, New Delhi after getting approval from the Competent Authorities.

**6.11.16 The Committee takes note that the Central Council for Research in Siddha has identified a key concern area in management of cancer i.e. side effects of cancer therapy faced by cancer patients during their illness. The Committee recommends that the institute expedite research studies under its "Pharmacovigilance" program that helps detection, prevention and management of drug-induced adverse reactions. The Committee also recommends the Ministry to fast track establishment of Siddha Integrative Palliative Care Therapy in CCRS, New Delhi, and Safdarjung Hospital, New Delhi.**

#### **CCRH**

6.11.17 Although the studies to ascertain the efficacy and safety of AYUSH drugs in the management of cancer have not been undertaken on the management of side effects of cancer with homoeopathy have shown some positive outcomes. Also the OPD experiences on add-on homoeopathy in pain and palliative care treatment and treatment- induced mucositis have shown encouraging results. CCRH has earlier undertaken two clinical research studies on cancer ; ‘Role of individualized homoeopathy in combating the side effects of chemotherapy in cancer patients’ and ‘Clinical evaluation of homoeopathic medicines along with iscador therapy in managing malignant diseases’ with encouraging results. Based on these experiences, 03 clinical research studies are planned to be undertaken with Delhi State Cancer Hospital, Delhi and AIIMS, respectively as mentioned below-

- i. Phase II study to assess safety and effectiveness of using potentized form of chemotherapy (on-going with Apollo Hospital Chennai)
- ii. “Management of cancer patients experiencing mucositis from chemotherapy and radiotherapy with add on homoeopathy to usual care versus the usual care- A comparative exploratory study” (proposed)
- iii. “Homoeopathic treatment as an add-on therapy for pain management in cancer patients: A Prospective, Randomized, Exploratory study” (Proposed)
- iv. A Pilot Study Evaluating Role of Homoeopathic Medicine in Cancer Patients as Adjuvant Treatment to Chemotherapy/Radiotherapy, and Correlating with Molecular Profiling. CCRH has developed standard treatment guideline on cancer for profession to treatment patients suffering from cancer with adjuvant homoeopathy.

**6.11.18 The Committee takes into account the clinical research studies undertaken by CCRH for ascertaining the impact of homoeopathy in combating the side effects of chemotherapy in cancer patients’ and its efficacy in management of Cancer. The Committee recommends the Ministry to document and publish the outcomes of such**

**clinical research studies and further encourage clinical research studies on Homeopathy so as to have enough scientific validation of the Homeopathic measures on management of Cancer. The Committee also intends to know the Ministry's vision for translation of the findings of the clinical research studies on Homeopathy into Clinical practice and how the integration within different Ayush verticals for management of cancer is being envisioned.**

### **Ayurgyan**

6.12 The Ministry of AYUSH is running a Central Sector Scheme namely AYURGYAN Scheme with two components, i.e., (i) Capacity Building & Continuing Medical Education (CME) in AYUSH (ii) Research & Innovation in AYUSH (erstwhile EMR Scheme) from the FY 2021-22. Under EMR Scheme, research projects were received and approved for research and studies to ascertain the efficacy and safety of AYUSH drugs in management of cancer.

**6.12.1 The Committee desires to be apprised of the measures taken by the Ministry under the scheme for capacity building, improving the quality of Ayush education and integration of Ayush education with the modern medical education. The Committee also recommends the Ministry to allocate more funds for the research work so that the efficacy and safety of Ayush drugs in management of cancer can be ascertained.**

### **Challenges and suggested approaches**

6.13 The Ministry of Ayush has submitted a number of challenges and suggestions for inclusion of Ayush into cancer care continuum as given below:

- i. Generating evidence of the benefits of Ayurvedic interventions through rigorous clinical documentation and well-conducted studies, especially targeting independent practitioners, researchers, and institutions engaged in integrative oncology service and research.
- ii. Publishing systematic reviews of prior research studies exploring the safety and efficacy of Ayurveda in the management of cancer.
- iii. Ensuring comprehensive clinical documentation of cancer patients using Ayurveda treatment as a standalone or add-on therapy based on categorization of patients.
- iv. Setting up a clinical case registry for practitioners to report the clinical outcomes in treatment of cancer would be an important step to learn from the experiences of physicians who practice across the country.
- v. Conducting well-planned clinical trials that enable evaluation of the whole system approach in Ayurveda to understand the efficacy of the complete Ayurvedic intervention rather than individual components.
- vi. Conducting herb–drug interaction and chemo sensitivity studies based on both laboratory research and real-time clinical observations.
- vii. Establishing a database of medicinal plants and natural compounds showing promise in the management of cancer can facilitate in silico studies through bioinformatics tools.
- viii. Creating a trans disciplinary team of experts from the different healthcare systems who will collectively facilitate informed decision-making at the point of care. The

focus of the trans disciplinary team will be to achieve the goal of better treatment outcomes and QOL for the patients.

- ix. Addressing the medicolegal and ethical issues involved in integrative medicine and integrative Ayurveda oncology and developing guidelines for clinical practice and research.
- x. Making available insurance coverage for integrative oncology care, keeping in mind the goal of universal health coverage.
- xi. Establishment of a scientific body like ‘‘Society of Integrative Oncology’’ to bring together a multidisciplinary team of professionals to develop strategic policy/guidelines for integrative Ayurveda oncology in India.
- xii. Networking with global research and clinical community to integrate Ayurveda in the development of integrative oncology in the world.

**6.13.1 The Committee appreciates the Ministry of Ayush for identifying key concern areas in strengthening Cancer Care Plan and Management in Ayush. The Committee recommends the Ministry of Ayush for setting up a comprehensive framework to address these challenges on priority basis. The Committee recommends the Ministry to put concerted efforts in carrying out clinical trials adhering to the international guidelines/standards on clinical trials, such clinical trials would give the Ayush measures required legitimacy and scientific validation. The Ministry should also work towards creating a database of medicinal plants and natural compounds having potential for management of Cancer. Studies for testing the efficacy and safety of Ayush drugs along with modern medicine for management of cancer must be undertaken. The framework should also have provisions for addressing challenges posed by medico legal and ethical issues. Insurance coverage for integrative oncology care need to be made available for cancer patients. The Committee believes that even though integrative oncology is slowly evolving, efforts must be made by the Ministry to sort out areas of concern and address the visible challenges and help in creating an environment where Ayush can contribute in cancer management along with conventional treatment.**

6.13.2 The Committee notes specific suggestions of various Ayush institutions as enumerated below:-

#### CCRAS

- i. More rigorous research in preclinical and clinical domains for robust evidence generation.
- ii. Documentation of existing practices of ayurveda in cancer care by practitioners and analysis for further leads for research and care in cancer.
- iii. For Translation of evidence to practice, well equipped Ayush hospitals/ set ups with trained manpower are required
- iv. Training of the Ayush manpower in integrative oncology research and Cancer care
- v. Infrastructure development for delivering integrative services for cancer
- vi. Building the cross-referral system between Allopathy and Ayush for cancer.

6.13.3 According to NIA, Jaipur, there is a need to evaluate more Anti-Cancer Ayurvedic Drugs and evolution role of Ayurveda to prevent the genetic mutation through Ayurvedic Toxicogenetics required to strengthen the Cancer Care Plan & Management in AYUSH.

6.13.4 AIIA, New Delhi has suggested that a dedicated, experienced, exclusive manpower recruitment to the established centers with permanent post can be planned for sustained and progressive development which will run the OPD, IPD and also work on collaborative research projects.

6.13.5 NIH has suggested the following:

1. Diagnostics labs or centers may be identified by the Government where investigations like CECT, MRI, Histopathology etc for the Cancer patients may be done free of cost if referred by Government Ayush hospital or Institutes. Investigations are very important factor to keep a check on the progress of malignancy or to ascertain the efficacy of Ayush treatment. This will relieve the economical burden of the patient upto some extent.
2. Training: specially designed training may be given to the Ayush doctors to learn the diagnosis and supportive management of the cancer patients and special permission may be given to carry out Blood transfusion, Tapping etc and other lifesaving procedure after proper training.
3. Engagement of Allopathic medical officer in the Ayush hospitals: Emergency services/life saving procedures/ interventions are very important while treating a Cancer patient. Homoeopathic Physician is ethically not allowed to perform interventions like tapping (removal of fluid in ascites etc), blood transfusion and other life saving procedure while treating patients in the ward. This area can be attended if an Allopathic doctor will be there. This will help us to give better homoeopathic treatment and palliative care to the cancer patients.
4. Engagement of consultant Oncologist for Ayush hospitals. This will help in integrated approach in treating cancer patient.

**6.13.6 The Committee recommends the Ministry to take note of all the suggestions made by Ayush institutes for better management of cancer care by Ayush. The Ministry must provide all out support to these institutes from resources to adequate funding for ensuring training of Ayush manpower in integrative oncology, development of suggested infrastructure for the same, cost effective diagnostic labs for patients, engagement of oncologists, evaluation of Ayush drugs and cancer research.**

**6.13.7 The Committee would like to draw the attention of the Ministry of Health and Family Welfare and Ministry of Ayush towards Chinese traditional system of medicine which is properly integrated in conventional cancer treatment in China. The Committee, time and again, has been recommending integration of Ayush systems with modern medicine on similar lines as done in China and believes that such an integration would pave for holistic care of patients suffering from any disease which becomes all the more important in cancer care and management.**

## CHAPTER-VII

### PALLIATIVE CANCER CARE AND MANAGEMENT

7.1 The Palliative Care, also known as supportive care, is required in the terminal cases of Cancer, AIDS etc. and which can be provided relatively in simple and inexpensive manner in tertiary care facilities, in community health centres and even in patients' homes. Effective palliative care requires a broad multidisciplinary approach that includes the family and makes use of available community resources. It improves the quality of life of patients and families who face life-threatening illness, by providing pain and symptom relief, spiritual and psychosocial support from diagnosis to the end of life and bereavement.

7.1.1 The Ministry of Health & Family Welfare submitted that the need for palliative care is increasing at a rapid pace due to the world's ageing population and increase in chronic diseases. Accordingly, the Government is implementing National Program for Palliative Care (NPPC) which is a part of the National Health Mission (NHM). 580 districts/centres in 33 states/UTs have been supported under the program. Under the Ayushman Bharat Health and Wellness Centres, the 11th package is Elderly and Palliative Care for which detailed operational guidelines was developed and released in 2021.

#### **National Programme for Palliative care (NPPC)**

7.1.2 The NPPC has following objectives:-

- (i) Improve the capacity to provide palliative care service delivery within government health programs such as the National Program for Prevention and Control of Cancer, Cardiovascular Disease, Diabetes, and Stroke; National Program for Health Care of the Elderly; the National AIDS Control Program; and the National Rural Health Mission.
- (ii) Refine the legal and regulatory systems and support implementation to ensure access and availability of Opioids for medical and scientific use while maintaining measure for preventing diversion and misuse.
- (iii) Encourage attitudinal shifts amongst healthcare professionals by strengthening and incorporating principles of long term care and palliative care into the educational curricula (of medical, nursing, pharmacy and social work courses).
- (iv) Promote behaviour change in the community through increasing public awareness and improved skills and knowledge regarding pain relief and palliative care leading to community owned initiatives supporting health care system.
- (v) Develop national standards for palliative care services and continuously evolve the design and implementation of the National program to ensure progress towards the vision of the program

#### **7.1.3 The Implementation mechanism of the programme is as under:-**

- (i) It is envisaged that activities would be initiated through National Program for prevention and control of cancer, CVD, Diabetes & Stroke. The integration of national programs are being attempted under the common umbrella for synergistic activities. Thus, strategies proposed will provide essential funding to build capacity within the key health programs for non-communicable disease, including cancer, HIV/AIDS, and efforts targeting elderly populations. Working across Ministries of

Health and Finance, the program will also ensure that the national law and regulations allow for access to medical and scientific use of Opioids.

- (ii) The regulatory aspects, as mentioned in the program, for increasing Morphine availability would be addressed by Department of Revenue in coordination with Central Drug Standards Control Organization. Cooperation of international and national agencies in the field of palliative care would be taken for successful implementation of the program. The major strategies proposed are provision of funds for establishing state palliative care cell and palliative care services at the district hospital.

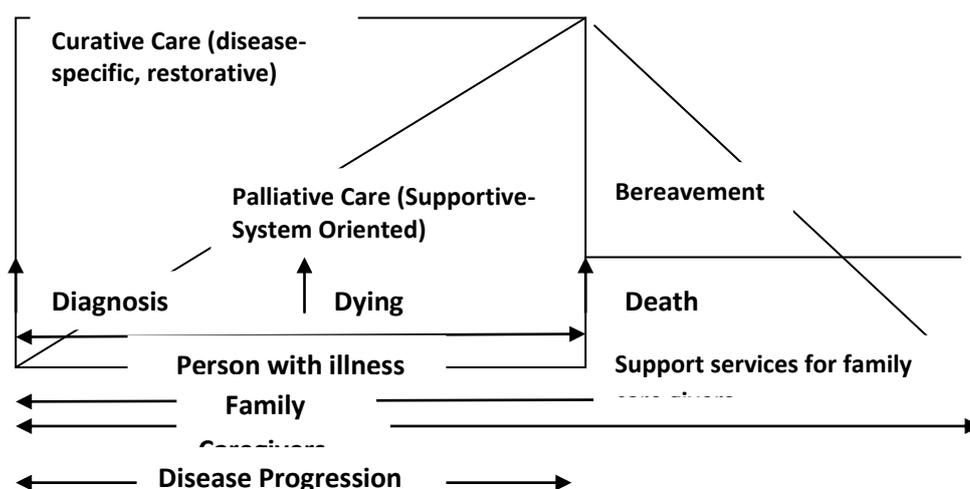
7.1.4 The Government of India (GoI) launched the National Program for Palliative Care (NPPC) in 2012. Ever since then Government of India has been earmarking funds under NRHM flexi pool for initiating and scaling up palliative care services in various states depending on the Program Implementation Plan submitted by each state. The NPPC strategy is in line with 2014 World Health Assembly Resolution for achieving universal access to palliative care as part of Universal Health Coverage (UHC). As per WHO, Palliative care is an approach that improves the quality of life of patients and their families facing the problems associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual.

7.1.5 Palliative care is required for patients with a wide range of life-limiting health problems. The majority of adults in need of palliative care have chronic diseases such as cardiovascular diseases (38.5%), cancer (34%), chronic respiratory diseases (10.3%), AIDS (5.7%) and diabetes (4.6%). Patients with many other conditions may require palliative care, including kidney failure, chronic liver disease, rheumatoid arthritis, neurological disease, dementia, congenital anomalies and drug-resistant tuberculosis.

7.1.6 As per WHO estimates each year, an estimated 40 million people need palliative care, 78% of whom live in low – and middle-income countries. Worldwide, only about 14% of people who need palliative care currently receive it.

7.1.7 Palliative Care, when indicated, is fundamental to improving the quality of life, well – being, comfort and human dignity for individuals. It is the responsibility of health system and health care professionals to alleviate pain and suffering, whether physical, psychosocial or spiritual, irrespective of whether the disease or condition can be cured.

7.1.8 If cure is not possible, palliative care provides essential care resulting in pain relief, control of symptoms, and the minimizing of suffering. Figure below illustrates a “continuum of care” for cancer, HIV/AIDS, and other life-limiting diseases:



7.1.9 The Service Delivery Framework for Palliative care under NCCP programme covers the following:-

Individual/Family/Community level:

- As part of the population enumeration and empanelment process, ASHAs will identify bed-ridden patients and others needing palliative care.
- Such individuals are visited by the Multi-Purpose Worker (MPW)/Community Health Officer (CHO) for a further assessment using the Palliative Care Screening tool.
- MPWs, ASHAs, Community volunteers and family are trained in ‘Communication skill’ ASHAs and volunteers undertake periodic, home visits to the patients and support to the patient and family members. Families are be assisted with routine home care, simple nursing skills and accessing various service as needed including mobilization of local resources.

7.1.10 ASHA is expected to play the following role in providing palliative care:

- Create awareness about palliative care, First level Screening of patient/families for potential palliative care needs
- Identify and refer patients to the Community Health Officer (CHO) as required Identify community volunteers for palliative care
- Work with MPW to deliver basic patient management services
- Provide general support to the families/patients
- Escort the patient/family during initial visits to ensure better liaison between beneficiary and service providers
- ASHA will continue to visit the beneficiaries identified by her for Palliative care services.

- ASHA and MPW will utilize meetings of the Jan Arogya Samiti/Village Health Nutrition and Sanitation Committee/Mahila Arogya Samiti (VHSNC/MAS) to raise awareness about the needs of palliative care patients, and mobilize individual and community level support, including accessing assistance available through other Government programmes.

- The CHO will undertake social and behaviour change communication effort in general community and specific groups (teachers, panchayat members, NGOs, youth

groups and women self-help groups) in order to recruit volunteers for palliative care services in her/his HWC coverage area. ASHA and MPW will identify a group of volunteers in her service area. Volunteers could be drawn from Youth Groups, Mahila Mandals, Co-operatives, Non- Governmental Organizations, etc. A social behaviour change communication training of such volunteers could be undertaken by the CHO /Staff nurse or Medical Officer at HWC – SHC or PHC/UPHC. Willing volunteers are trained in simple nursing skills. The list of trained volunteers to be displayed at prominent locations in the HWC area including the health facility, schools, anganwadis, ration shops, panchayat office etc to enhance the credibility and pride in the volunteer. Certificates are given to the volunteers for providing home based palliative care.

- A simple format for the same for the documentation of Palliative Care Services is provided for ASHA. She submits the same at the Sub Centre as part of her monthly report.
- The MPWs are trained to assess symptoms and undertake basic nursing tasks like dressing of the foul smelling wound, bladder catheter change etc. She should also be able to communicate compassionately with the patient and family, answering all their queries with knowledge, patience and understanding.
- Caregivers (family) can also be equipped to perform simple nursing tasks.
- ANM/MPW to refer those needing a more thorough assessment to the CHO.
- CHO to conduct home visit and assess the patient/family.

Health Promotion including the use of IEC for Behaviour Change Communication:

- a) Collaborate with NGOs to act as technical advisory agencies for the process of community awareness, mobilisation and empowerment in the field of palliative care programs.
- b) Empower the palliative trained staff to orient and educate care-givers/family members in providing home-based care.
- c) Empower Community Based Organizations and families in continued care for the patient through structured care & support educational activities.
- d) Ensure involvement of the Local Self Government Institutions/PRI's through sensitisation workshops for the members.
- e) Sensitize healthcare professionals in private and public-private health facilities.
- f) Conduct awareness/sensitization programs for regulatory and administrative nodal 11 officers. Professional organisations like Indian Association of Palliative care and NGOs could be co-opted for this.
- g) Ensure active support from the media.

### **Human Resources: Mapping of providers to Services for Palliative Care**

7.2 Considering the varied dimensions of palliative care, a package of essential services is to be made available at each level of care. Volunteers play a very important role at each stage, especially in provision of social and spiritual care. Other team members can also provide psycho-social-spiritual care based on their capacity or training. For those in psychological distress not manageable by primary palliative care interventions will be referred to a clinical psychologist or Psychiatrist available in District Hospital. The packages of essential palliative care services provided at various levels are summarized in table below:-

<b>S.No.</b>	<b>Palliative Care Provider</b>	<b>Components of essential service package</b>
1.	JAS/VHSNC/MAS/RWA	<ul style="list-style-type: none"> <li>(i) Awareness for Palliative care and the importance of volunteers for Psycho-social-economic-spiritual support</li> <li>(ii) Help families with routine home care</li> <li>(iii) Help in accessing various service as needed including mobilization of local resources</li> <li>(iv) Bereavement support</li> </ul>
2.	ASHA	<ul style="list-style-type: none"> <li>(i) Identifying patients/families for palliative care needs</li> <li>(ii) Help families with routine home care</li> <li>(iii) Help in accessing various service as needed</li> <li>(iv) Networking to assure community support</li> <li>(v) Referral services</li> <li>(vi) Encourage VHSNC/JAS/MAS/RWA to provide bereavement support</li> </ul>
3.	MPW/ANM	<ul style="list-style-type: none"> <li>(i) Assessment of patient/families by home visits</li> <li>(ii) Perform basic nursing procedures</li> <li>(iii) Supporting–caregivers/ASHA/ Volunteers</li> <li>(iv) Compassionate communication and Counselling</li> <li>(v) Provide basic medications as per instructions from Staff Nurse/MO</li> <li>(vi) Referral services</li> <li>(vii) Bereavement support</li> </ul>
4.	Staff Nurse/CHO (H&WC(SHC)/PHC/CHC)	<ul style="list-style-type: none"> <li>(i) Detailed assessment of patient/families by home visits</li> <li>(ii) Perform basic nursing procedures</li> <li>(iii) Training of the caregivers/ASHA/Volunteers/ANM.</li> <li>(iv) Dispense medication as per the prescription of MO to palliative care patients excluding Narcotic Drugs.</li> <li>(v) Conduct weekly outpatient clinics in H&amp;WC or PHC/UPHC</li> <li>(vi) Referral &amp; Linkage services for complex cases</li> <li>(vii) Data management for entire H&amp;WC /PHC /CHC – rural and urban</li> <li>(viii) IEC activities</li> <li>(ix) Compassionate communication and counselling</li> </ul>
5.	Medical officer (PHC/CHC – rural and urban)	<ul style="list-style-type: none"> <li>(i) Detailed assessment of patient/families by home visits or Outpatient basis</li> <li>(ii) Perform basic procedures [Ryle’s Tube Insertion, Urinary Catheter Insertion, Ascites Tapping, Complex wound dressing, Colostomy Care, Tracheostomy Care etc.]</li> <li>(iii) Training of the caregivers/ASHA/Volunteers/ANM/ Staff Nurse.</li> <li>(iv) Prescribe medication to palliative care patients</li> </ul>

		including Essential Narcotic Drugs. (v) Conduct weekly outpatient clinics in HWC &/or PHC/UPHC (vi) Manage palliative care patients referred to PHC/UPHC (vii) Referral & Linkage services for complex cases (viii) Supervision of all palliative care activities under his/her unit. (ix) Compassionate communication and Counselling
6.	Staff Nurse (District Hospital)	(i) Primary management of complex cases (ii) Inpatient management of cases (iii) Training of all sub-district level healthcare functionaries in palliative care. (iv) Compassionate communication and Counselling
7.	Medical officer (District Hospital)	(i) Management of complex cases (ii) Inpatient management of cases (iii) Training of all sub-district level healthcare functionaries in palliative care. (iv) Compassionate communication and Counselling
8.	Specialized Palliative Care Centres (Including Medical Colleges)	(i) Specialized Palliative Care Services (ii) Inpatient care (iii) Research & Training (iv) Policy & Advocacy

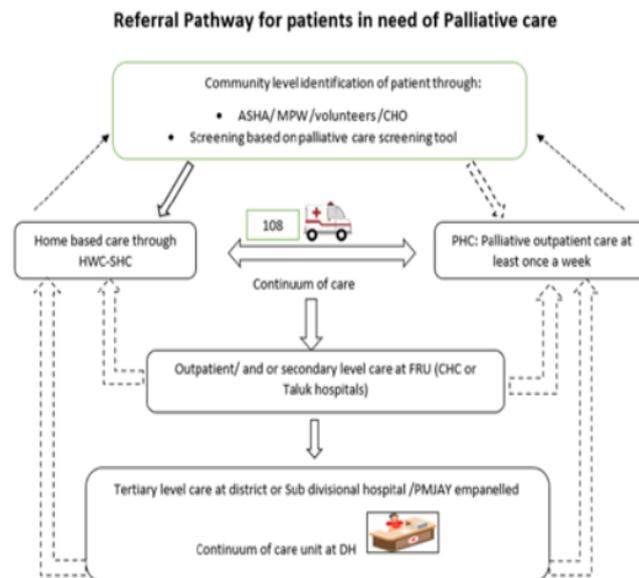
### Capacity Building plan

7.3 Training of entire healthcare team and infrastructure would enable incorporation of palliative care at all levels of health care delivery so as to meet the demand. Since the Comprehensive Primary Health Care mainly focuses on the primary and secondary levels of care givers, with active engagement of the community, more stress is to be given to the training programmes for various categories of health care providers at the basic and mid-levels and community volunteers. A cascade model of training is to be imparted where National, State and District trainers are trained in Elderly and Palliative care in a combined package. ASHA requires 6 days of training and MPW-F, Community Health Officer and Staff Nurse requires 5 days of training at block level. Medical Officer will need training for a period of 4 days in a tertiary care setting. The State Program Officer plan and implement a training schedule for all the above as per the training guidelines and train materials provided. The services of reputed Palliative Care Organisations in the county may be harnessed for efficient delivery of quality training. Additional training material for various categories of healthcare personnel are available at [https://dghs.gov.on/content/1351\\_3\\_NationalProgramforPalliative\\_Care.aspx](https://dghs.gov.on/content/1351_3_NationalProgramforPalliative_Care.aspx)

### Monitoring and Supervision

7.4 Reporting is done by using format prescribed by Central Division to report physical and financial progress made under the different components of the program by the state and the district at regular intervals. In addition to this, the State Program/Nodal program officer or the

Co-ordinator of the program in the State Palliative Care Cell visits the districts regularly for monitoring.



7.4.1 The Ministry further submitted that the Standard Protocols for Palliative Care in India have been developed by the Ministry. Training manuals for doctors and nurses have also been developed to sensitise medical officers and nurses from District Hospitals/Community Health Centres/Primary Health Centres towards delivery of Palliative Care services. Master trainers, consisting of 22 doctors and nurses from 11 states/UTs have been trained/sensitized. A training manual for Community Health Workers like ASHAs, ANMs, MPWs and CHOs have also been developed. State level ToTs have been conducted in 7 States.

7.4.2 Certain amendments were effected in Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985 in 2014, which shall allow:

- i. A single regulation for morphine & other Essential Narcotic Drugs(ENDs);
- ii. A single license to hold and use ENDs;
- iii. A single agency – the State Drugs Controller – to issue licenses and monitor it.

7.4.3 The Government of Karnataka Palliative Care Policy approved in 2016 includes that all the cancer treatment centres need to have palliative centre. During the visit of the Committee to Bengaluru, the Kidwai Memorial Institute of Oncology (KMIO), in their presentation, submitted that in India due to low awareness about cancer, a large proportion of cancer patients report at an advanced stage of the disease, where definitive treatment options are highly restricted. Managing symptoms, enabling patients to improve quality of life and living pain free, are a few goals of palliative therapy.

7.4.4 A large number of people die with pain and suffering that can be avoided with adequate treatment. Limited access to pain medications, lack of palliative care, trained health professionals, weak national level policies on palliative care are few important areas to be addressed to improve accessibility to this form of care. In KMIO, a palliative care department is providing training for Doctors, Nurses, Social workers and Health workers to increase the manpower in palliative services.

7.4.5 The Committee is given to understand that Kerala has been acknowledged as a successful model, not only in India but in the entire developing world, through its path-breaking work in Community Based Palliative Care. Kerala State Palliative Care Policy 2009 states that the Palliative Care movement in Kerala had its roots in NGO action which soon attracted a high level of political ownership. Kerala declared Palliative Care Policy in 2008.

7.4.6 The Committee is given to understand that the Government of Kerala has integrated palliative care with healthcare policy at all levels in a three-tier system. Local governments and over 350 non-government and community-based organizations are now providing Palliative Care services, largely home-based. The Committee observes that the Kerala Model places a strong emphasis on community participation and volunteerism integrated with Primary Health Care system especially through dedicated nurses under the overall leadership of local governments.

7.4.7 The Committee notes that Palliative care in India is still at a very nascent stage except the State of Kerala that boast of a comprehensive Palliative Care Services. The Committee takes into account that lack of a robust National Palliative Care Policy and institutional arrangement in palliative care across States has resulted in neglect of the Palliative care in India. The Committee understands that with increasing incidence of chronic lifestyle diseases and cancer, there is a need to change the approach to palliative care and bring in a comprehensive policy.

7.4.8 The Committee is of the opinion that along with an institutional hospital based approach led by health professionals, the Ministry must also explore the possibility of adopting community based care at macro level in the country. The Committee, accordingly, recommends the Ministry to integrate palliative care with the healthcare policy at all levels and make active use of the community based resources. The Committee recommends the Ministry to increase community engagements and participation from civil society. The Committee may also explore the involvement of Private Sector in starting independent Palliative care institutions in different communities. There is a need to develop a mechanism wherein the trained professional can identify patients' needs and provide home care at all levels.

7.4.9 The Committee further finds that pain relieving drugs form important part of the Palliative care. The Committee notes that the Indian Government has recently allowed private companies in the strictly regulated sector of processing opium which is used to make medicines for relieving cancer pain. The Committee reckons that there are risks associated with opium addiction and its illicit trade, however, the Committee believes that making such drugs available in Cancer Centers for pain control is crucial for providing better Palliative Care. The Committee, therefore, recommends the Ministry to ensure that effective measures are taken to ensure that cancer pain controlling medication is easily available at Palliative Care Units and Cancer Centres.

7.4.10 National health systems are responsible for including palliative care in the continuum of care for people with chronic and life-threatening conditions and linking it to prevention, early detection and treatment programmes. Hence there is a need for developing health system policies that integrate palliative care services into the structure and financing of national health-care systems at all levels of care. Policies are required for strengthening and expanding human resources, including training of existing health professionals, as well as educating volunteers and care takers. A medicine policy which ensures the availability of essential medicines for managing

**symptoms, in particular opioid analgesics for the relief of pain and respiratory distress is required.**

**7.4.11 The Committee is agreement with the views of the National Cancer Institute, Jhajjar on the Palliative Medicine front, which has been designated as the WHO centre for next five years. The Committee recommends that the policy of the Government should be that each medical college should have a Palliative Medicine Department and the availability of Morphine and technical expertise to prescribe Morphine must also be present throughout the country.**

#### **Palliative Cancer Care by AYUSH Systems**

7.5 The Ministry of Ayush has submitted that AYUSH Public Health KARUNYA (AYUSH Palliative Services) has been included in the revised guidelines of NAM. Its objective is to ensure quality assured, integrated supportive palliative care for the needy patients including chronic diseases like Lifestyle diseases, Geriatric patients, Differentially abled persons, Psychiatric patients, CVS patients etc. Supportive Palliative care can be given anywhere - at home or in the hospital. Homecare is considered better because patients are more comfortable in their own home. It is cheaper and the family can take care without having to travel. Supportive Palliative care can be provided through AYUSH Dispensaries/Health & Wellness Centres (HWCs), secondary level AYUSH Hospitals or the referral hospitals, along with the patient's regular treatment. It should be a part of existing AYUSH healthcare at all levels of care. Low cost, effective supportive palliative care can be delivered as part of primary care even in far-off areas. Palliative care should be started early, preferably from the time of diagnosis. This helps build trust, plan ahead to prevent symptoms and have timely discussions with the family. It helps plan for good end of life care by making wise, well-informed and timely decisions when the disease is advanced.

7.5.1 The beneficiaries of Palliative care are those with Cancer, Stroke or spinal cord injuries, Chronic neurological diseases e.g.- Parkinson's disease, Old age conditions like Alzheimer's disease, Children with cerebral palsy or birth defects, Psycho social supports for Organ failures like heart failure, lung failure or kidney failure, Auto immune diseases like Systemic Lupus Erythematosus, Rheumatoid Arthritis, Multiple Sclerosis, HIV/AIDS, any other condition which require palliative care as per the strength of AYUSH systems of medicine.

7.5.2 Implementation of National AYUSH Mission comes under the purview of respective State/UT Governments. Accordingly State/UT Governments may avail financial assistance by submitting the proposal through State Annual Action Plans (SAAPs) as per NAM guidelines.

7.5.3 The Committee has also been given to understand that the Ayurveda interventions along with panchakarma modalities may be used for the palliative cancer care. Many of the Ayush hospitals have such facilities and these should be upgraded through the strengthening of the manpower in terms of training in integrative oncology and also engaging oncologists as a member in the team in the Ayush hospitals. Ayush has a fair presence in the rural and remote areas through its Ayush medical officer at Ayush dispensaries of NRHM and NAM. The trained manpower in integrative oncology and the upgraded facility will definitely deliver good palliative cancer care to the needy in the remote and rural area in more economical way. These need - training and empowerment of Ayush faculty and engagement of modern oncologist wherever possible. The institutional Ayurveda Cancer Consultation & Treatment Unit at NIA, Jaipur have dedicated team for palliative cancer care. This National Institute

have had organized the Cancer Awareness campaign, Health Check & Medical Camp to proliferate the AYUSH Care for Cancer to the rural and remote area. Palliative care for cancer patients can be done in Integrative Cancer Care Unit of AIIA, however presently there is no exclusive palliative care clinic established at AIIA.

7.5.4 Further, several Research studies on Yoga & Naturopathy have shown beneficial effects in chronic diseases like cancer with respect to reduction of side effects of cancer treatment, psychological stress levels, biochemical parameters & enhancement of QoL and Immune status in cancer patients. NIN, Pune is already providing all non-pharmacological palliative therapies of Naturopathy and Yoga through its OPD and also to the tribal population through its Tribal Unit at Gohe village. CCRUM is providing palliative cancer care in Unani Medicine through a network of 18 clinical institutes/Units/ Centres spread all over India.

7.5.5 Palliative care is the emerging field in AYUSH and CCRS officers have got trained and started using palliative care practices. In this regard CCRS has released cancer care manual and also have taken part in Protocol Development for Palliative care. The Swasthya Rakshan Programme is being conducted to provide health care facilities at the remote/rural areas at present under Ministry of Ayush by all the Research Councils. The same system can be utilized through mobile units to provide cancer care w.r.t screening, follow up and prevention strategies in primary and tertiary health care centres. Siddha Integrative Palliative Care is planned in Siddha Unit (CCRS) New Delhi, along with the Cancer Dept of Safdarjung Hospital, New Delhi after getting approval from the Competent Authorities.

7.5.6 CCRH under the integrated National Program for Prevention and control of cardiovascular diseases, diabetes, cancer and stroke from 2015 to 2021 wherein few patients suffering from cancer sought homoeopathic treatment. The integrated pilot project was implemented at rural/urban set up in four districts Krishna District, Andhra Pradesh, Darjeeling district, Siliguri, Sambalpur district, Odisha and Nashik district, Maharashtra. Homoeopathic treatment as an add-on to conventional treatment at Palliative Pain Clinic, Safdarjung Hospital was provided to the patients from June 2017 to March 2020. Based on the OPD experience, it is suggested that Homoeopathy has a supportive role in management of pain and other associated complaints in patients seeking palliative care, thereby improving quality of life. Further studies are required to define the exact role of Homoeopathy. National Institute of Homoeopathy, Kolkata treats and gives palliative care to the cancer patients. This can be proliferated to the rural and remote area by engaging Post Graduate Homoeopathy doctors in PHCs, CHCs, Sub centers etc.

**7.5.7 The Committee acknowledges that the Ministry has come up with Ayush Palliative services- KARUNYA and has included it in the National Ayush Mission. The Committee is of the opinion that palliative care in Cancer is very important as it plays a vital role in providing relief from pain and other distressing symptoms, it also aims to integrates the psychological and spiritual aspect of patient care.**

**7.5.8 The Committee believes that Ayurveda interventions should be used for the palliative cancer care. The Committee recommends that palliative care facilities at Ayush hospitals should be upgraded through the strengthening of the manpower in terms of training in intra-Ayush integrative oncology. The Ministry should further improve its presence in the rural and remote areas and further train and empower Ayush faculty as trained manpower in intra-Ayush integrative oncology and the upgraded facility will definitely deliver good palliative cancer care to the needy in the remote and rural area in more economical way. The Committee also recommends that**

facilities for palliative care for cancer patients on the lines of Integrative Cancer Care Unit of AIIA, should be established in other institutes under the Ministry of Ayush.

**7.5.9** The Ministry may also apprise the Committee about findings of the research studies on Yoga & Naturopathy and how they have fared in reduction of side effects of cancer treatment and improving of psychological stress levels. The Committee further recommends that all non-pharmacological palliative therapies of Naturopathy and Yoga should also be started in all the Health and Wellness Centres of Ayush. The Ministry may also apprise the Committee about the details like number of patients benefited, number of care givers and Unani professionals working in the 18 Unani clinical institutes providing palliative care in Unani medicine.

**7.5.10** The Committee notes that the Ministry of Ayush through its research council runs "Swasthya Rakshan Programme" to provide health care facilities at the remote/rural areas and the same can be utilized for providing similar facilities like screening, follow up and prevention strategies through mobile units to cover rural and remote regions of the country. The Committee appreciates this initiative of the Ministry and recommends it to further expand the outreach of such mobile units to rural and remote areas for cancer prevention and screening.

#### **Medical Cannabis as Alternative Medicines**

**7.5.11** The Committee has been given to understand that western countries are now waking up to the benefits of medicinal cannabis as the first line agent for management of pain, nausea and other specific symptoms including chronic pain, epilepsy, chemotherapy induced nausea and vomiting, symptoms associated with terminal illness, sleeplessness, anxiety, depression etc.

**7.5.12** The Committee has been informed that there are presently two cannabis products - cannabidiol (CBD) and tetrahydrocannabinol (THC). Both these products have huge potential for palliative care of cancer patients by giving pain relief as well as a sense of peace in terminally ill-patients without the side-effects associated with other medicines. Both these products have the potential to improve the quality of life of cancer patients. Hence, a concerted effort by all concerned stakeholders starting from Government to the Legislature, Pharma companies, Research Institutes to Medical professionals need to consider using such alternative medicines to give terminally ill cancer patients to live a life with dignity.

## CHAPTER-VIII

### VIEWS OF THE MINISTRIES/DEPARTMENTS/NGO's/PRIVATE HOSPITALS AND PRIVATE SECTORS

8.1 During the course of its deliberations on the subject, the Committee held meetings with Ministry of Health and Family Welfare, Indian Council of Medical Research, Government Departments like Department of Pharmaceuticals, Department of Atomic Energy, and Department of Biotechnology. The Committee also heard the views of several research institutes and hospitals *viz.* Dr. Bhubaneswar Borooah Cancer Institute (BBCI), Guwahati, Assam, Chittaranjan National Cancer Institute, Kolkata, National Institute of Cancer Prevention & Research, Gautam Buddha Nagar, Uttar Pradesh, National Cancer Institute, AIIMS, Jhajjar, Haryana.

8.1.1 The Committee also sought written views of several major stakeholders on the subject. In response, the Committee received some worth-mentioning written responses from hospitals like Fortis, AIIMS, Raipur, Apollo hospitals, Pfizer Ltd., Novartis Healthcare and several NGOs like CAN Support, Progressive Foundation etc. Some suggestions of stakeholders have already been utilized by the Committee while formulating its views/ observations/ recommendations as various aspects of Cancer care and management in preceding chapters, however, certain attention drawing suggestions have been dealt in this chapter rechristened as remaining issues.

#### **Ministry of Chemicals and Fertilizers**

8.2 The Ministry of Chemicals and Fertilizers in its submission to the Committee, while mentioning that ICMR has not conducted any study to find out the reasons for increase of cancer cases in the country, stated that it cannot be concluded that there is direct correlation of consumption of higher agrochemicals *i.e.* Pesticides with increasing incidence of cancer.

8.2.1 The Committee is given to understand that in 2016-17, the pesticides consumption (kg per Sq Km) was highest in Punjab (116.02), Haryana (91.60), Puducherry (90.48), Delhi (59.30), J&K (51.79). However, the incidence of cancer in these states is not as high as in other states/UTs.

**8.2.2 The Committee desires that DHR should undertake a project to study and find out reasons for increase of Cancer cases in the country, region-wise and Cancer-site wise in male and female. The study may also look for any direct correlation of consumption of higher agrochemicals *i.e.* Pesticides with increasing incidence of cancer.**

#### **Ministry of Environment, Forest and Climate Change**

8.3 The Ministry informed that non-communicable diseases including cancer are emerging as major public health problems in India. The risk factors of the major non-communicable diseases (Diabetes Mellitus, Cardiovascular Diseases, Diabetes, and many types of Cancer) are tobacco, dietary habits, inadequate physical activity, occupational exposure, alcohol consumption, immunity and heredity of individual etc. Exposure to certain chemicals and radiations are also the risk factors for cancer.

8.3.1 The Ministry apprising the Committee of the initiatives in prevention of exposure to carcinogenic pollutants mentioned that India has notified the health based National Ambient Air Quality Standard (NAAQS) for twelve parameters, in 2009. As regards the initiatives on

waste management, the Ministry informed that it frames policy and regulations, and promotes Environmentally Sound Management of wastes, viz., Solid waste, E-Waste, Bio-medical waste, Ash, Construction & Demolition Waste, Hazardous Waste, etc. and in this direction has notified several rules.

8.3.2 The Ministry has banned Single Use Plastic (SUP) from 01.07.2022. To prevent use of harmful pesticides and industrial chemicals (Persistent Organic Pollutants), the Government of India has ratified the Stockholm Convention, a global treaty to protect human health and the environment from Persistent Organic Pollutants (POPs).

### **Progressive Foundation**

8.4 Cancer has the greatest out-of-pocket costs due to its chronic nature and costly treatment. The therapy costs frequently force families deeper into debt and most of the times end in financial disaster. Ensuring the accessibility of medication for these families is an essential part of their Right to Health. Reducing the GST applicable on cancer medicines from 12% to 5% will ensure accessibility in three ways; first, it will ensure these medications are more affordable; second, it will ensure these medicines are more accessible for economically vulnerable sections of society; and third, it will improve accessibility in isolated regions. Moreover, due to better access to lifesaving medicines, there will be decrease in morbidity and mortality resulting in fewer burdens on overall healthcare budget.

8.4.1 The Government should formulate a policy according to which a corpus/fund for supporting cancer patients especially those who are not covered under any scheme should be formed. This kind of additional support would be a boon for cancer patients.

**8.4.2 The Committee is in agreement with the suggestions of Progressive Foundation that the Government should create corpus/fund for supporting Cancer patients under any scheme. This scheme may invite donation from philanthropic sources as well as from Corporate Social Responsibility (CSR) contributions of the companies. The Committee feels that provision for Cancer cess/ transport toll for cancer should also be considered.**

### **Amrita Institute of Medical Sciences**

8.5 Incidence of cancer is very high in India and majority are under reported. As there are less structured facilities in smaller cities and rural India, affordability of treatment significantly affects the utility of the facilities.

8.5.1 There is a need to first prioritize the basic infrastructures in all rural and urban population with 100% coverage. Basic investigation and screening facility at rural and urban hospitals should be established with at least one basic diagnostic facility within 25 KM radius. These screening facilities should have trained oncologists at rural oncology facilities. A biopsy and immune-cyto-chemistry (IHC) facility should be developed at block level hospitals along with CT scan / MRI scan facility. Also, Palliative care facility should be established at block or primary health care facility.

8.5.2 For diagnoses, the stress should be on methods of early detection with a clearly defined pathway for further management once diagnosed. All medical colleges should be encouraged to adopt a village or taluk or district depending on their capabilities and promote cancer

prevention and early detection there. All medical colleges should also have a community oncology department and palliative care division.

8.5.3 Patients with early disease detection and likely to be cured, need to be treated with 'state of the art' facilities. There is a need for a referral policy for curable patients in tertiary facilities or academic centres. There is a need for 'state of the art' equipment and expertise in academic and tertiary centres.

8.5.4 Insurance schemes like the Ayushman Bharat PM-JAY should be promoted. Better compensation packages which are more rational, insisting on guideline based treatment and putting a cap on some packages should be considered. The treatment portability with the power to transfer their medical documents given to the patient should be made possible in the near future. People who avail of screening for cancer should get greater concessions in the insurance, so that this acts as an incentive for citizens to participate in the screening as per guidelines.

**8.5.5 The Committee concurs with the suggestions of the Amrita Institute that the Government must focus on methods of early detection with a clearly defined pathway for further management once diagnosed. The Government may encourage medical colleges to adopt a village, block, town or district to promote ways and means for cancer prevention and encourage people to undergo screening. The Ministry should also work on establishing 'state of the art' equipment and expertise in academic and tertiary centres for Cancer treatment. The Government may also consider better compensation packages which are more rational, insisting on guideline based treatment and having a cap on pricing of certain therapies/treatments under the Ayushman Bharat scheme. Further such packages should also include treatment portability with the power to transfer the medical documents of the patients to their choice of hospital/treatment facility.**

#### **Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST)**

8.6 Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) has maintained a uniquely altruistic tradition of subsidized services to the financially poor and vulnerable, mainly due to Government aided schemes – Ayushman Bharat -PMJAY scheme, Rastriya Arogya Nidhi (RAN) and Health minister's discretionary grant (HMDG). Governmental support both from central and states apart from the philanthropic efforts of individuals and corporate organizations fund the treatment for the weaker sections of the society seeking oncology related services. Various cancers of the brain and spinal cord are evaluated and treated at SCTIMST. These include primary tumours of the brain, primary tumours of the spinal cord and secondary deposits from cancers of other organs which get entry in to brain through the blood stream. It is very essential to provide total tumour clearance before the patient is subjected to other modalities of treatment like chemotherapy and radiotherapy. The institute also offers state of the art diagnostic services to diagnose and follow-up cancers involving the brain, lungs and other organs.

#### **Rajiv Gandhi Cancer Hospital, Rohini, New Delhi**

8.7 The hospital made the following suggestions:

- i. Lack of awareness amongst people, lack of prioritization of health by the Central and State Governments, delay in diagnosis due to poor screening and inequitable access to

affordable curative services are some of the major concerns in cancer treatment in India.

- ii. The awareness about Cancer should start at school and colleges, chapters about cancer being curable at early stages, cancer being preventable should be included, along with projects, and debates etc. in the school curriculum, also the knowledge should be imparted at community level.
- iii. Open discussions should also be organized and encouraged in all social platforms—through messages, videos, advertisements of products. The population of the country, children and youth in particular should be informed about healthy lifestyle and healthy diet.
- iv. The Government should also consider introducing vaccination for cervix cancer in school health program. The main focus of the cancer prevention activities has to be directed towards the villages in cooperation with the District Health Centres and Primary Health Centres.
- v. The cost of Cancer management is mainly on the initial diagnostic tests, cancer drugs and end of life care. These costs are higher in India as majority of patients are diagnosed at advance stages due to lack of adequate awareness and unavailability of coordinated screening and prevention strategies available to them.
- vi. If standard guidelines are followed this would greatly help in providing cost effective care. A central body similar to that in UK i.e. “National Institute of Clinical Excellence” is much needed in the country which can look at the interventions of guidance but also look at the cost effectiveness.
- vii. Emphasis should be laid to encourage government support for indigenization of diagnostic tests, expensive equipment (diagnostic and therapeutic) through a public private partnership.

**8.7.1 The Committee recommends the Ministry to put concerted efforts for inclusion of Chapter on Cancer/ Non Communicable Diseases in Environmental Studies and Ecology in middle, secondary and senior secondary classes. The Chapter must include aspects like awareness about Cancer, preventive measures, different causes of Cancer, importance of screening and early detection etc. Children and youth of the country should be informed about healthy lifestyle and healthy diet.**

**8.7.2 The Government should also consider establishing an Indian Institute of Clinical Excellence which can look at formulating Standard Treatment Protocol (STP) and guidelines and other ways for cost-effectiveness of treatment methods.**

**Jawaharlal Institute of Post Graduate Medical Education and Research (Jipmer), Dhanvantri Nagar, Puducherry**

8.8 The Institute made the following suggestions:

- i. India has a high number of cancers of breast (30 per 1 lakh population), mouth, throat, lung, uterine cervix (15 per 1 lakh population) and others. The preventable ones are tobacco-related (throat, mouth, lung cancers) and infection-related (cervix). For some cancers like colorectal cancer (intestinal cancer), finding them at an early stage of the disease could help reduce deaths. The methods of cancer prevention include tobacco-control, HPV vaccines, screening for common cancers like mouth, breast and colon. The screening methods could be implemented in two ways - at the population level and at the hospital level.

- ii. Tumor Boards involving doctors from all related branches like surgical, radiation, medical oncology, gynecology, ENT, dental surgeons and others provides the best possible diagnosis and most appropriate available treatment to patients at the individual level. Also, dedicated cancer follow up clinics within the institutions can address the issue of diagnosing residual/relapsing cancers which is usually more difficult otherwise. Dedicated pathologists and radiologists need to be included in the oncology team in all cancer hospitals to improve the accuracy of diagnoses.
- iii. Despite having over 1 million new cases of cancer per year, the research output in India is much behind nations like USA, Europe, Australia and China. To improve the research scenario the research should focus on problems relevant to our country, cancer which are common here as well as presentations which are unique here. Research should be on issues like the unique genetic and epigenetic signatures of cancers in India and the pharmacogenomic differences.
- iv. Also, there are very few cancer drugs which are primarily developed in India, the regulatory environment requires a change to encourage new drug development, indigenous development will reduce the cost of drugs. The Government through relevant bodies like BIRAC, DBT, and DST should provide more support for development of real world evidence (RWE) as many cancers are rare and it will be difficult to have randomized trials for all cancers.
- v. The Government must streamline the insurance schemes like AB-PMJAY, to include more people in it. Even for people not in BPL category, cancer and its therapy prove to be very expensive. The insurance scheme of Government needs to be accordingly updated to include most of the Indians in it.
- vi. More support is needed for development of bio-similar and generic molecules which can reduce the cost significantly. Despite DPCO by NPPA, the gap between MRP and actual supply price is huge for many cancer drugs. Private hospitals gather massive profits by collecting MRP rates or a bit less than MRP rates. More work needs to be done to regulate the price of cancer drugs.

**8.8.1 The Committee agrees with the view of JIPMER that regulatory environment in the country requires a change to encourage new and indigenous drug development for Cancer which can reduce the cost of drugs. The Committee recommends that Government through relevant bodies like BIRAC, DBT, and DST should provide more support for development of real world evidence (RWE) as many cancers are rare and it will be difficult to have randomized trials for all cancers. The Committee notes that despite DPCO (Drug Price Control Order) by NPPA, the Ministry should put in more efforts to regulate the price of cancer drugs in the country.**

#### **AIIMS, Raipur**

8.9 The hospital made the following suggestions:

- i. Cancer data is essential so that timely, accessible, high-quality care and prevention can be provided to patients.
- ii. Cancer data is used to know the expected number and types of cancer patients, and it is also used to know the cost of treatment and supportive care. It is also used to plan human resources.
- iii. Cancer data are used to track decreases in new cancer cases associated with measures to reduce exposure to a known risk factor. It is also used for comparisons.

- iv. Public expenditure on Cancer in India remains below US \$10 per person (compared with more than US\$100 per person in high-income countries), and overall public expenditure on health care is still only slightly above 1% of gross domestic product. Out-of-pocket payments, which account for more than three-quarters of cancer expenditures in India, are one of the greatest threats to patients and families, and a cancer diagnosis is increasingly responsible for catastrophic expenditures that negatively affect not only the patient but also the welfare and education of several generations of their family.
- v. Bibliometrics can provide a good method to understand, calibrate, and compare research outputs and activity within and between countries. In 2011, the National Cancer Grid of India commissioned a full analysis of all scientific outputs that arose from cancer research done in India. Research papers were processed for the Web of Science.
- vi. The percentage of review articles from Indian authors rose from 2% in the 1990s to higher than 8% in recent years.
- vii. Indian cancer researchers are improving their reputation compared with the rest of the world. Such conclusion is supported by the increases in international contribution in Indian cancer research output—only 5% of the total in 1990–94, but 9.6% in 2000–04 and 11.0% in 2010.
- viii. The five-time rise in output from India over the past 20 years parallels the rise in output from other developing Asian countries.
- ix. However, collaboration occurs at a lower rate than might be expected for a country with a relatively small scientific output in which international partners could provide complementary skills and experience.

### **Indian Cancer Society, Mumbai**

8.10 The Society made the following suggestions:

- i. A disease as severe as Cancer is a notifiable disease only in few states namely TN, Karnataka, Rajasthan, Kerala, Manipur and Sikkim. The need of the hour is to make cancer notifiable in the entire country.
- ii. Notification of cancer will lead to better understanding of common preventable causes and optimum utilization of health resources with better monitoring and evaluation of the effectiveness of health programs such as cancer screening and cancer treatment programs, which ultimately might improve survival.
- iii. For cervical cancer elimination, the most important area of Govt intervention is cost of HPV vaccine, making it affordable and available is a priority.
- iv. Family physicians must be trained and sensitised to the cancer specific education. Involving the family physicians as important stakeholders in the cancer care continuum, is the need of the hour.
- v. With the Govt. nudge, the pricing control mechanism of cancer drugs can be strengthened and hospitals can be encouraged to take advantage of the reduced prices for the benefit of their patients.
- vi. GST Council is already looking into reduction of GST on cancer drugs; however, the benefit must be passed on to the patient who is the central point of a proposed value-based care.

- vii. Presently, all the Government schemes both at the Central and the State level are primarily for BPL section. A strong effort should be made to have some provision for patients from middle income group and who are not covered under any Government or private insurance.
- viii. Lastly, the revised CSR guidelines by the Govt. has reiterated the mandatory contribution of 2% towards Corporate Social Responsibilities. In this regard a directive to suitably prioritise the CSR funds for Cancer Care activities should be made.

**8.10.1 The Committee is dismayed with the fact that all the Government schemes both at the Central and the State level are primarily for BPL section. The detection of cancer to any family member brings the whole family to poverty. The Committee, accordingly, recommends that concerted effort should be made to have provisions for cancer treatment of patients from middle income group who are not covered under any Government or private insurance scheme.**

**8.10.2 The Committee has been given to understand that under the revised CSR guidelines by the Government there is provision for mandatory contribution of 2% towards Corporate Social Responsibilities. In this regard, the Committee recommends the Ministry to co-ordinate with the relevant Ministry and release a directive to suitably prioritise the CSR funds for Cancer Care activities.**

#### **Mahavir Cancer Sansthan, Patna**

8.11 The Sansthan made the following suggestions:

- i. Awareness of basic Health providers and common people about early cancer detection, for this medical camps in rural areas should be organised which should have the provision for screening of cancer, the doubtful cases of cancer should be referred to the nearest diagnostic facility.
- ii. For better prevention, cancer awareness programs in schools and colleges should be organised and campaign against tobacco and alcohol should be started.
- iii. People should be encouraged to adopt healthy diet and practice physical activity and general hygiene, cleanliness to prevent infection.
- iv. Supply of pure and safe drinking water should be ensured.
- v. Incorporation of vaccination against HPV and HBV in National Immunization Schedule.
- vi. Early diagnosis remains the key to survival in cancer. Efforts to make public aware of suspicious signs and symptoms of cancer should be made, for this orientation courses in oncology should be started for health care workers working in rural and semi-urban areas so that the diagnosis is not delayed.
- vii. Similarly, training initiatives by cancer centres and oncologists should be taken and telemedicine should be used for suspicious cases by health care workers working in peripheries.
- viii. Work on mapping of cancer centres with available facilities so that patients can have an early referral should be done. Furthermore, cancer screening in routine health care packages should be incorporated.
- ix. Provisions for basic and clinical research in cancer in the form of grants and help for proposal writing.
- x. Focused areas of research for cancer common to particular geographical region.

- xi. Collaboration/MoU between Government education and research institutions and cancer centres should be initiated.
- xii. More efforts to develop indigenous kits and drugs to diagnose and treat cancer should be put.
- xiii. Cancer centres should be set up in areas with high incidence of cancer and group negotiations for cancer drugs and radiotherapy machines should be considered.
- xiv. There is urgent need for development of national treatment protocols and guidelines with use of minimum investigations.
- xv. Indigenous development of machines for diagnosis and treatment should be encouraged.
- xvi. Proper outcome analysis of cancer patients treated with advanced techniques and new drugs in late stages of the disease should be done.
- xvii. Patients need not travel large distances for getting symptomatic treatment, such facilities should be developed in different regions of the country.

### **CANSUPPORT, New Delhi**

8.12 CanSupport is largest palliative care organisation in the country with the mission of improving the quality of life of those with advanced cancer. The disease has become the second largest killer in India with nearly 8 lakh deaths annually. While a big reason is that many patients are first diagnosed in a late stage, another is that most are unable to afford the costs of treatment. Lifesaving drugs for cancer treatment are priced exorbitantly and are out of reach of the common man.

8.12.1 It is suggested to permanently abolish tax on these drugs in their large interest to reduce their financial pain in the face of other physical emotional, social and spiritual suffering they are undergoing due to a cancer diagnosis. Permanently reducing the GST rate on these life saving cancer treatment drugs will not only give impetus to the government's universal healthcare agenda but will also benefit millions of poor cancer patients of our country.

### **St. Jude India Child Care Centre**

8.13 The Centre made the following suggestions:

- i. Need for Home away from Home for children undergoing treatment for cancer
- ii. Recognizing Home Away Home (HAH) as a separate category will help in the establishment of many such homes and ensure that the facilities operate under appropriate regulatory and legal framework.
- iii. St. Judes has been fortunate to be have tied up with Star Health Insurance for a pilot project to offer a group insurance policy for paediatric cancer survivors who have stayed at St. Judes centres during their treatment.
- iv. The Primary Health Centres should be equipped and trained to identify the symptoms to reduce delay in diagnosis and commencement of treatment.
- v. The Ayushman Bharat Scheme has greatly enhanced support for medical treatment for underprivileged families. The Scheme should be extended to include diagnostic tests.

## **Cancer Awareness, Prevention & Early Detection (CAPED) Trust**

8.14 The Trust made the following suggestions:

- i. Reducing the GST to 0-5% will make cancer medicines and treatment affordable for more patients.
- ii. Patient Assistance Programs (PAPs) assists those patients who are not covered under either any government schemes or covered by insurance.
- iii. HPV vaccine has the potential to prevent more than 90% of HPV-attributable cancers. Vaccinating girls before the age of 15 reduces the risk of cervical cancer by 88%.
- iv. With increased Aayushman Bharat coverage and inclusion of middle class under this scheme will enable more people to afford treatment, leading to a better cancer survival rate.
- v. Making cancer screening a mandatory part of all health insurance schemes at zero out of pocket cost
- vi. Making cancer a Notifiable disease
- vii. Initiating a Cancer Fund to financially support treatments and therapies and implementing a transport/toll/CESS.

## **Cancer Foundation of India**

8.15 The Foundation made the following suggestions:

- (i) The merger of the National Cancer Control Programme (NCCP) into the NPCDCS has reduced the focus and proper handling of cancer screening required in the country. Therefore, cancer requires a separate programme outside the NPCDCS.
- (ii) Although the NPCDCS is a population-based programme, its implementation on the ground is mainly opportunistic.
- (iii) The proper linkages between the screening NCD clinic and cancer care and treatment facility at a TCC or State Cancer Institutes (SCI) or a government hospital with cancer treatment facilities are generally missing.
- (iv) To expand the coverage of accurate cancer incidence data,
  - Cancer is made a notifiable disease in all the states
  - Establish PBCRs in states/regions that have remained so far uncovered.
  - HPV vaccine be immediately included in the Universal Immunization Programme (UIP), the population based national immunisation programme in the country.
  - An education-based comprehensive community awareness program is initiated to improve public knowledge of cancer risk factors, signs, and symptoms.
  - Comprehensive training through competent trainers in public health institutes in the country is needed to be developed to prepare a highly trained and motivated cadre for health promotion, prevention, and early detection.
  - All efforts be undertaken to bring about a behaviour change in society for

tobacco control. This would allow an efficient implementation of anti-tobacco laws in the country.

## **APOLLO Hospitals**

8.16 The hospital made the following suggestions:

- i. Besides prevention, early detection methods, screening and treatment, the awareness plays a very important, may be the most important role in cancer control.
- ii. Integrated national labs dedicated to early diagnosis are required. National reference labs for Radiology, and Pathology mandated for diagnosis of the screening patients must be formed.
- iii. Centralized labs in all regions will report/ collate the data of the radiology and pathology cytology or biopsies. Screening should to be linked to AYUSHMAN schemes or AADHAR cards or Health cards.
- iv. Public-Private sector partnership for extensive epidemiological research
- v. Strengthen low-cost alternatives to high-cost imported drugs and study their efficacy in Indian populations (chemotherapy, targeted therapies, immunotherapies etc)
- vi. Develop cancer therapies/drugs in India specific to Indian population.
- vii. Incentives/tax benefits to encourage R&D across pharmaceutical industry
- viii. Studies on already available cost-effective drugs (Different protocols etc.) for other indications
- ix. Studies to increase accessibility to immunotherapy for Indian cancer patients
- x. Effective collaborative cancer research between public and private sector cancer centres to generate data/evidence for optimal cancer therapy in various fields of cancer epidemiology, screening/prevention, surgery, systemic therapy, radiotherapy, diagnostics, integrated cancer care etc
- xi. Need to shift focus from Volume driven strategy to the value based medicine wherein the focus should be on the patient.
- xii. For Accessible Affordable Cancer Care, the goal of the government should be to reduce disparities in access to cancer care for vulnerable and underserved populations. This can be achieved by developing a national strategy that leverages existing efforts by public and private organizations and by supporting the development of innovative programs. Also by identifying and disseminating effective community interventions and by providing ongoing support to successful existing community interventions.

**8.16.1 The Committee is in agreement with the view that integrated national labs dedicated to early diagnosis should be established preferably in all the districts of the country. Similarly, national reference labs for Radiology, and Pathology mandated for diagnosis of the screening patients must be formed.**

## **Fortis Healthcare Limited**

8.17 The hospital made the following suggestions:

- i. Advocacy on Cancer Awareness and knowledge building on early warning signs/symptoms (both for primary care physicians and patients).
- ii. Need of training of pathologists for cancer diagnosis (at nodal/tertiary centres) and increase in manpower of doctors and technicians.
- iii. Establish comprehensive cancer centres (at least a 50-bedded) for each region/district to increase ease of access and improve treatment compliance.
- iv. More radiotherapy facilities in smaller cities and towns. At present there is gap of 1200 linear accelerators for the present cancer burden in India.
- v. Resource allocation for research in India is low. Need to enhance funding & support for Clinical Trials. Research culture needs to be strengthened.
- vi. Price capping of expensive anti-cancer drugs and equipment has enhanced affordability.
- vii. Lower duties on devices used in cancer diagnosis & treatment such as Radiation machines, X-Ray, CT scan; MRI; PET-CT; Radioisotopes have resulted in wider use of these machines and lower pricing for consumers. However, there is scope for further reduction, thereby, making cancer care much more affordable.
- viii. Tax cuts on expensive equipment such as Linear Accelerators; PET-CT etc. would reduce fixed cost and encourage setting up of new cancer centres across India.

**8.17.1 The Committee recommends that the Government must seriously consider tax cuts on expensive equipment such as Linear Accelerators; PET-CT etc as this would considerably reduce fixed cost and encourage setting up of new cancer centres across India.**

## **Pfizer Products India Private Limited, Mumbai**

8.18 There are innovative targeted therapies for oncology treatment now available that are more effective by engaging with the target/tumor in question with fewer side effects. This is a paradigm shift from the traditional approach to cancer treatment. The current New Drug and Clinical Trial Rules 2019 (NDCT 2019) do provide for expedited pathways based on existing global approvals for such drugs, however, these exemptions are subjective and often not provided. There should be seamless and defined timelines for expedited approval pathway for oncology drugs in India. In order to ensure there is no delay for patients to access the innovations in oncology care available across the world, there is a need for reliance on global clinical data to expedite drug approvals rather than duplication of Phase 3 clinical trials in India before approvals. Duplication of Phase 3 trials leads to an average delay of 1.5 to 2 years in the launch of new cancer drugs. This pathway is already provided in the NDCT Rules in Rule 101 which allows for waiver of local Phase 3 clinical trials for a new drug if it has been approved in the countries specified.

8.18.1 It is, therefore, recommended that Government may operationalize Rule 101 of the New Drug and Clinical Trial Rules 2019 (NDCT 2019), which allows the Drugs Controller General of India (DCGI) to specify certain countries (with well-regulated clinical trial processes and governance mechanisms) for considering waiver of local clinical trials for

approval of new drugs. Thus, urgent notification of countries to operationalise Rule 101 for all oncology therapies can play a key role in expediting oncology drug approvals.

8.18.2 Approval of anti-cancer drugs follows the established approval pathway as stipulated by the Central Drugs Standards Control Organization (CDSCO). These approval processes can be further strengthened by making them time-bound, predictable, and transparent in implementation. It is therefore suggested that a Standard Operating Protocol may be created for the conduct of SEC and TRC meetings – to include minimum required guidelines on participation, timelines and time-bound disposal of matters. Also, a single window system leading to submission of all documents at one go rather than the current stepwise process should be created. Furthermore, all documentation and processes for submission for approvals may be aligned to global formats and standards

8.18.3 At present Cancer medicines lie in the 12% bracket of GST. Even in the pre-GST era, there were excise & VAT exemptions given by states like Maharashtra, Assam etc. which led to an effective tax of 5% on Cancer medicines. But with implementation of GST regime this has added a 7% increase in cost burden on patients or loss of almost one month therapy which is very crucial from a patient perspective. Hence placing Cancer medicines in the NIL or 5% tax slab is desirable.

**8.18.4 The Committee is of the view that the Government should consider exempting certain drugs originating from countries having well-regulated clinical trial processes from local clinical trials; this would help in expediting oncology drug approvals. Similarly, approval processes for anti-cancer drugs should also be further strengthened by making them time-bound, predictable, and transparent in implementation.**

#### **ROCHE Pharma India**

8.19 The Company made the following suggestions:

- i. To treat and manage cancers of various types, doctors use surgery, chemotherapy, radiotherapy, immunotherapy and targeted therapy. From a drugs perspective, newer forms of treatment like immunotherapy and targeted therapy are driving significantly positive outcomes for cancer patients, and are now-a-days the preferred standard-of-care globally. Patients in India should also have access to these newer forms of treatment options to manage their condition better.
- ii. Given the complexity in manufacturing and stringent requirements, most of these innovative treatment options are manufactured at specialised plants in different parts of the world from where they are supplied to different countries worldwide. Today, these products, while delivering significant health benefits to patients also attract Customs duty and GST, adding to their treatment costs.
- iii. To drive broader access, pharma companies today make their innovative therapies available at a price that is set according to individual country specific rules and requirements, based on the context of each country. The price in India is at a significant discount to global pricing. Additionally, to drive broader access, companies proactively offer Patient Support Programs (PSP) in India where patients get a host of benefit to help manage their condition.
- iv. A full waiver of Custom duty and GST for cancer drugs will enable companies to pass on the benefit to patients so that their cost of therapy comes down significantly and ensure that a large number of patients with Cancer in India can afford these innovative therapies to

manage their condition better and lead better lives. This would further complement existing PSP efforts of companies, enabling timely, long-term access and affordability for patients in their fight against Cancer.

8.19.1 In summary, some of the areas the government should focus on for Cancer Care Plan and Management are:

- i. Enable access to standard-of-care treatment which will deliver better outcomes for patients
- ii. Manufacturing of innovative cancer therapies is an incredibly complex process. A pragmatic approach may be adopted regarding what can be made locally and balance it with what can be made available through imports while ensuring affordability.
- iii. The government should work with the industry on a regulatory framework that encourages global pharma companies to launch their innovative treatment options in the market at the earliest
- iv. Increase access to medicines by working on sustainable funding options, including
  - a. Increasing funding for cancer treatment by having a dedicated program for cancer
  - b. Introduce a subsidised insurance rider for cancer coverage on all existing and new health insurance policies
  - c. GST & Custom duty waiver/ reductions on cancer drugs to reduce the cost burden on patients.

### **Confederation of Indian Industry (CII)**

8.20 The Confederation made the following suggestions:

- i. Despite spending humongous efforts and resources on spreading awareness about cancer and its causes, the prevalence of cancer disease has shown a rising curve over the years. With the changing world, various enterprises have introduced innovative ways to spread awareness among the masses. Some of them include social media and online advertisements.
- ii. Vaccination against Human Papilloma Virus (HPV) for girls in the eligible age group can substantially reduce the cervical cancer incidence to near elimination levels in the foreseeable future. HPV protect the next generation of women from this cancer by building up successive cohorts of women at low risk for HPV infection.
- iii. Connecting the health and wellness centers under the Ayushman Bharat initiative to the regional cancer center (RCC) in a hub-and-spoke model, could fasten the time to diagnosis and delivery of efficient care.
- iv. There are less than 1000 formally trained medical oncologists in India, mostly concentrated in the top Tier-1/Metro cities. Digital technology could play a huge role in developing a network that connects expertise at the top of the pyramid to where it is most required, i.e., at the grassroot level.
- v. Adoption of Health Technology Assessment strategies for reimbursement and pricing of innovative therapies will help expand access to innovative products and therapies that can deliver better outcomes and quality of life for cancer patients.
- vi. Latest advancements in technology like artificial intelligence (AI), Internet of things (IoT) have the potential to affect several facets of cancer care, making it more accessible and accurate. Integration of AI technology in cancer care could improve the accuracy and speed of diagnosis, aid clinical decision-making, and lead to better

treatment outcomes.

- vii. About forty percent of cancer hospitalization cases are financed by informal financial tools. A major part of this comes from availing informal credit at shockingly high rates of interest. This, combined with a high mortality rate in Cancer, the net outcome for the household happens to be an insurmountable debt staring at them while having lost the earning member of the family. Therefore, easily accessible credit line through formal channels is highly needed to fill this gap and currently, there are few such medical/healthcare loans options available in the Indian market. But these are primarily offered by Non-Banking Financial Companies (NBFCs). Since, their risk appetite is quite limited, the cost of capital (interest rate) is as high as 13% to 15% and the loan limit is not more than INR 25 lakhs. This again raises a concern of affordability. Hence, it is imperative to encourage major and nationalized banks to create such product which is affordable for the public to use it as an emergency fund.
- viii. PAP is usually designed and sponsored by pharmaceutical companies to offer free units of the medicine against a unit purchased for the class of patients who are non-reimbursed or do not have sufficient insurance coverage which results in improved patient access and compliance with treatments. There is no involvement of trade channels, and it does not include trade margins. Inclusion of free supply under PAP for the purpose of calculation of PTS artificially brings down the MRP as fixed by NPPA to unviable levels. This will naturally lead to companies stopping PAP. In such an event, the effective price of the medicine will increase for the concerned therapy areas

#### 8.20.1 Key Recommendations:

1. Encouraging corporate and nationalized banks for creation of more credit tools to meet catastrophic healthcare needs in critical care segments;
2. Stacking of funding schemes for an increased depth of coverage for critical care;
3. Rationalization of various taxes and duties on certain categories of medicines to make cancer medicines and treatment affordable;
4. Effective rationalization of trade margins and exclusion of free supply under PAP for the purpose of calculation of PTS; and
5. Allowing a PPO exemption for non-local suppliers in case of patented, specialty and proprietary drugs not produced in India

#### **MSD Pharmaceuticals Pvt. Ltd**

8.21 The gap between the required and current growth in cancer care infrastructure in India cannot be addressed through an incremental and linear approach. The health, social and economic challenges of the cancer epidemic, both historical and contemporary, must be met by a holistic and integrated approach. The key areas of the program includes 4 aspects i.e. prevention, screening, diagnosis and treatment which has the direct impact on the cancer care management. Whereas awareness, affordability, research and policy reforms act as the enablers which would have an impact on the 4 key areas of cancer care management.

The recommendations made are summarized below:

- i. Prioritize inclusion of HPV vaccination under National Immunization Plan;
- ii. Integrating awareness and screening in the early detection pathway at PHC level;
- iii. Leveraging low-cost innovative technology to drive mass awareness and screening;

- iv. Establish decentralized diagnostic network to enable increasing capacity and quality of diagnostic facilities at point of care with digitally enabled referral mechanisms;
- v. Extending coverage for diagnostic services under PMJAY including confirmatory diagnostic tests and genomic profiling;
- vi. Support creation of a seamless, interoperable and integrated data system to enable adoption of HTA strategies for pricing and reimbursement of innovator therapies;
- vii. Establishment of clinical decision support systems at specialist centers for better in-clinic patient management and protocol driven care;
- viii. Leverage technology to enable evidence-based treatment choices and provide protocol driven care at the point of care;
- ix. Encouraging corporate and nationalized banks for creation of more credit tools to meet catastrophic healthcare needs in critical care segments;
- x. Stacking of funding schemes for an increased depth of coverage for critical care;
- xi. Rationalization of various taxes and duties on certain categories of medicines to make cancer medicines and treatment affordable;
- xii. Effective rationalization of trade margins and exclusion of free supply under PAP for the purpose of calculation of PTS;
- xiii. Allowing a PPO exemption for non-local suppliers in case of patented, specialty and proprietary drugs not produced in India;
- xiv. Need for a National Policy to Catalyse Research & Development and Innovation in the Pharma Sector in India;
- xv. Greater policy alignment with the guidelines developed by International Conference of Harmonisation;
- xvi. Adoption of Reliance Pathways for reducing TAT for approvals in India;
- xvii. Improvising section 3D to avoid patent grant delays;
- xviii. Access to adequate information on the CDSCO website w.r.t. pending applications;
- xix. Enhanced data points available for access through RTI Act;
- xx. Exemption patented drugs from National List of Essential Medicines (NLEM).

### **Kidwai Memorial Institute of Oncology**

8.22 The hospital made the following suggestions:

- i. It is Prudent to evolve a National Childhood Cancer Comprehensive Management Policy which involves Early Diagnosis, Shared Care, Integrated Paediatric Oncology Palliative Care across the Public Health Facilities. It is pertinent to note that Sri Lanka evolved a National Strategic plan on Childhood & Adolescent Cancer. All the involved stakeholders may be invited to evolve a Plan/ Policy.
- ii. The Stakeholders are Indian Council of Medical Research, WHO India Office, UNICEF India Office, Indian Academy of Paediatrics-Paediatric Haematology Oncology Chapter and Directors of all the Regional Cancer Centres in India. However, a single implementing agency of Ministry of Health and Family Welfare which has presence at the State/UT Government Level also need to be identified. It is suggested that Rashtriya Bal Swasthya Karyakram (RBSK) is the most appropriate programme for the same.
- iii. Furthermore, a large gap is found in radiotherapy infrastructure. In India, less than 20% of the patients receive radiation treatment on an average, due to lack of access and affordability concerns. Radiotherapy is one of the three pillars of cancer treatment, along with chemotherapy and surgery, and is a highly personalized, targeted, and cost-

effective form of treatment. Thus, while the use of Radiotherapy services exists as an effective tool to treat cancer, it is not leveraged fully in India. This further results in patients having to travel long distances to access treatment, further adding to financial burden and a large share dropping out of treatment.

- iv. Given constrained financial resources, innovation partnership models need to be utilised to ensure the system is capable of delivering access to treatment. Further, focus on integrating existing programs will be the key.
- **Public Private Partnership:** A model which defines the role of each member for purchasing and installing requisite equipment across institutions. The model will also be capable of completing all activities to make a centre operational including receiving required clearances required from AERB.
  - **Patient Treatment** – The model is structured to meet the goal of providing treatment at affordable rates to the patient population as well as delivering financial viability in a reasonable time period. In this regard, two areas would need to be considered –
    - **Patient Types** – in order to ensure a viable patient mix, the project may consider three types of patients that may seek treatment at the facility, (i) patients being treated at the cost of the government through an existing insurance scheme or other mechanism, (ii) a middle tier of patients who are willing to “co pay” or subsidize cost of treatment and (iii) self-paying patients.
    - **User Charges** – rates for treatment may be determined using the defined rates under the Ayushman Bharat scheme (or rates as per the alternate State health insurance scheme); or in the absence of both, as per the rates charged under the Central Government Health Scheme (CGHS). Rates may be fixed at the appropriate stage following a thorough financial analysis (in partnership with state authorities).
    - Costs may be brought down by group negotiation for construction activities, equipment, drugs, and consumables.
- (v) A dedicated program that generates demand will serve to incentivise manufacturers to participate in programs such as Make in India and sector specific Production Linked Incentive Schemes (including for cancer devices).
- (vi) As the Government increases its focus on reducing import dependence for medical devices, models such as localization through technology transfer and/or licensing arrangement with an existing public manufacturing institution may be explored. This presents a clear advantage for the country to enhance its science and technology base in a cutting-edge area of medical science.

**8.22.1 The Government is in agreement with the view that the Ministry must work towards formulating a National Childhood Cancer Comprehensive Management Policy which involves Early Diagnosis, Shared Care, Integrated Paediatric Oncology Palliative Care across the Public Health Facilities. The Committee recommends that the Ministry may revamp the Rashtriya Bal Swasthya Karyakram (RBSK) to include the provisions of Cancer Care, treatment and Management.**

## Postgraduate Institute of Medical Education and Research, Chandigarh

8.23 The hospital made the following suggestions:

- i. Cancer management is a multidisciplinary service which needs a highly interactive and co-operative work amongst, medical oncologists, surgical oncologists, radiation oncologists and Once-diagnostic services.
- ii. There is a remarkable deficiency of subject expert in the field of Medical and Surgical Oncology in various hospitals and academic medical centres in India. As a result, many cancer patients are unable to get benefit from services of multidisciplinary tumor board for their seamless management. There is published evidence which suggest that patients treated by a multidisciplinary tumor board have better clinical outcome and survival. Therefore, in every medical college, a department/unit of Medical and Surgical oncology must be created and well-defined tumour board must be designated which would deliver cancer care to every patient. If the tumour board at a regional centre faces difficulty, then the case be referred to a tertiary care centre for further evaluation and management.
- iii. There is also a need to have a policy of reverse-referral to the regional cancer centre once the tertiary level care is provided. Every district hospital needs to be equipped with the facility of infusion of standard chemotherapy protocol. As an institute of national importance, PGIMER is willing to mentor and train existing medical staff of district hospitals for administering standard chemotherapy and to manage patients with basic side-effects of anticancer treatment.
- iv. PGIMER proposes the development of early detection clinics at all district hospitals in collaboration of oncologist with the Public and Social Health Department. These clinics need to be equipped with screening facilities as well as outreach vehicles which can provide screening services at the doorstep.
- v. The current diagnostic facilities need augmentation in all major regional hospitals. There is a need of developing image guided biopsy facility along with immunohistochemistry testing at every medical college level.
- vi. There is an urgent need to develop India specific guidelines for management of cancer patients in our country. As the developments in the field of cancer are happening at a fast pace, PGIMER suggests measures to support and expedite review and funding process for all cancer related research projects.
- vii. PMJAY has given remarkable support to cancer patients and a significantly large number of patients are able to receive the frontline treatment for majority of the cancers. PGIMER suggests that for tertiary level centres like PGIMER, AIIMS, Tata Memorial Hospital and JIPMER etc. there should be a provision for reimbursement of second line regimen as well. These centres have large burden of patients who have relapsed/refractory malignancies and they need advanced treatment.
- viii. Making expensive biological therapies (targeted therapies, immunotherapy) affordable: An effort at the government/administrative level may be necessary to carry out discussion and negotiations with the manufacturers of these newer therapeutic interventions (novel targeted drugs and immunotherapeutics) so that these are available to patients coming to PGIMER, Chandigarh (as well as government funded health care facilities) at

highly discounted rates. These would enable eligible patients (including lung cancer patients under treatment the department) to have access to highly effective treatment strategies and potentially improve both survival and quality of life while simultaneously avoiding chemotherapy in many cases.

**8.23.1 The Committee recommends the Ministry to improve the Cancer screening, diagnostic and treatment infrastructure of the PHCs, CHCs and District Hospitals. Every district hospital should be equipped with the facility of infusion of standard chemotherapy protocol. Similarly, every medical college in the country must be provided facility for image guided biopsy facility along with immunohistochemistry testing. The Committee recommends the Ministry to encourage the tertiary facilities like AIIMS, PGIMERs, SGPGI and other medical institutes of national importance to mentor and train existing medical staff of district hospitals for screening, diagnosing, administering standard chemotherapy and to manage patients with basic side-effects of anticancer treatment.**

**8.23.2 The Committee appreciates the efforts of Stakeholders in enlightening the Committee Members on various aspects of Cancer care, treatment and Management. The suggestions of stakeholders have been well taken by the Committee while considering various issues concerning the Cancer care and management and based upon these suggestions, the Committee firmed up its observations and recommendations. Still, there is a possibility that certain valuable suggestions of the Stakeholders might have missed the attention of the Committee. Therefore, the Committee urges upon the Government to pay heed to those suggestions of the Stakeholders too, while formulating Policy and Guidelines on Cancer care, affordability, treatment, research and palliative care for Cancer patients.**

## RECOMMENDATIONS/OBSERVATIONS-AT A GLANCE

### INCIDENCE OF CANCER CASES

#### Cancer Registries

The Committee is constrained to express its deep displeasure over the fact that the National Cancer Registry Programme (NCRP) is working since 1982 through Population Based Cancer Registry (PBCR) and Hospital Based Cancer Registry (HBCR) but only 10% of Indian population is covered under PBCRs. The Committee strongly believes that there is an urgent need to have more rural based PBCRs to get realistic information about the incidence and type of cancers across the country. The Committee recommends National Centre for Disease Informatics and Research (ICMR) to take requisite action to set up population based cancer registry in rural areas in the States viz. Uttar Pradesh, Madhya Pradesh, Andhra Pradesh, Rajasthan, Telangana, Orissa to ensure coverage of population by registry in these States. Such requisite action is all the more necessary to collect data & information not only for policy making on cancer treatment but also for uniform distribution of cancer care.

(Para 1.5.2)

The Committee notes that Population Based Cancer Registries (PBCRs) are a critical component for cancer control strategy that facilitates accurate information on cancer burden. Realizing that PBCRs help in better planning and formulation of National Cancer Control Programmes, the Committee notes that many areas remain under represented in the existing cancer registries. The Committee therefore recommends the Ministry to take measures to expand the scope of PBCR and ensure conducting more rural based PBCRs to get accurate information about the incidence and types of cancer across the country.

(Para 1.5.4)

The Committee recommends the Ministry to ensure that with the expansion of PBCRs, all the regions are adequately represented and an unbiased cancer registry is created. The Committee also recommends for integration of the real-time health records on a digital platform like a central registry system so that the data can be accessed across the country and there is no duplication. Such integration is crucial for better understanding of the cancer burden in the country.

(Para 1.5.5)

The Committee notes that Cancer is still not classified as a notifiable disease which results in underreporting of cancer deaths. The Committee notes that ambiguity on the actual cause of death is a major hurdle in data collection. It has been brought to the notice of the Committee that many a times; death is simply recorded as cardio-respiratory failure without mentioning the actual cause of death. The Committee is of the view that an accurate mortality database in the hospital information system will improve cancer registry, follow up and outcome data. The Committee therefore agrees with the suggestion of TMC that Cancer must be classified as a notifiable disease so that the cancer deaths are mandatorily required to be reported to the Government machinery.

(Para 1.5.7)

The Committee strongly believes that making Cancer a "Notified Disease" will surely ensure a robust database of the cancer deaths but also help in determining the accurate incidence and prevalence of Cancer in the country. It will also help in analyzing the risk factors, implementing screening programs, and allocating proper resources to improve cancer outcomes. Data collected can also be used to formulate standard treatment guidelines that will further strengthen the continuum of cancer care. The Committee further recommends that to streamline and improve data collection a CoWIN-like web portal for the registration, real-time data collection, counselling, supportive resources for cancer care along with interactive tools can be created by the Government. The portal can also be equipped to aid those affected by cancer by guiding them through the treatment and management journey.

(Para 1.5.8)

The Committee further recommends the Ministry to ensure the linking of Cancer Registry data with Ayushman Bharat / PMJY, mortality data bases, and the Hospital Information System (HIS) would improve cancer registration, follow up and outcome data.

(Para 1.5.9)

### **Causes of Cancer**

#### **High prevalence of Tobacco related Cancer (TRC) in the North Eastern States**

The Committee notes that the reason for high incidence of Tobacco related Cancer in the North Eastern Region is the high consumption of tobacco in the region. The Committee is appalled to note that tobacco consumption is as high as 60% in some North Eastern States against the National tobacco prevalence of 28%. The Committee further notes that the alcohol consumption in the North East is 28% which is more than double that of the National prevalence of about 12%. The Committee notes that as per the International Agency for Research on Cancer, alcohol is a confirmed cancer causing substance and the risk becomes higher when tobacco is consumed along with alcohol.

(Para 1.6.3)

The Committee is of the firm view that there is an urgent need to disincentivize the consumption of tobacco and alcohol in the country. The Committee accordingly recommends the Government to formulate effective policies on alcohol and tobacco control. The Committee also notes that India has one of the lowest prices for tobacco products and there is a need to increase taxes on tobacco products. The Committee accordingly recommends the Government to raise taxes on tobacco and utilize the additional revenue gained for cancer prevention and awareness.

(Para 1.6.4)

Attention of the Committee is also brought to the fact that more than 80% of tobacco consumption is in the form of chewing Tobacco with or without Areca Nut. These products are being aggressively marketed as mouth fresheners. The Committee accordingly recommends the Government to take measures to ban Gutka /Flavored Chewing tobacco/Flavored Areca (Pan Masala) and prohibit direct and indirect advertisements of Pan Masala.

(Para 1.6.5)

Taking into consideration that oral cancer being the highest contributor to the total cancer cases, the Committee observes that there is a need to implement the

provisions of Cigarettes and Other Tobacco Products Act 2003 (COTPA) more universally. The Committee notes that COTPA is the principal anti - tobacco law in India that encompasses a ban on smoking in public places, advertising and sponsorship, sales to minors, and warnings on packs. The Committee further notes that India's National Health Policy 2017 has set out to achieve a relative reduction in the prevalence of current tobacco use by 30% in 2025. The Committee believes to achieve the SDG target, the Ministry must take effective measures to contain the sale of Tobacco products. The Committee recommends the Government to abolish designated smoking areas in airports, hotels, and restaurants and encourage a smoke free policy in organizations. The Committee further recommends the Government to prohibit single stick sales of cigarettes and lay stringent penalties and fines on offenders.

(Para 1.6.6)

The Committee finds that the most common cancers like the oral cancer, breast and cervix cancer in women can be prevented and can be handled in a better way if they are detected early. However, lack of awareness and poor screening facilities delay the diagnosis and the cancer is detected at a fairly advanced stage. The Committee accordingly recommends setting up a robust screening mechanism at each level so that with early detection the cancer is cured completely.

(Para 1.6.7)

Keeping into account statistical interpretation of Comparative Age Adjusted Incidence Rates (AARs) of all PBCRs amongst men and women, the Committee recommends the Cancer Research Institutes to undertake Research Projects to understand the causative factors of gender specific cancer at specific site and come out with key solution to causation-continuum of cancer on cancer treatment.

(Para 1.7.6)

#### **Comparative Mortality: Incidence ratio in the country**

The Committee also notes that as per the Report on Medical Certification of Cause of Death 2020, medically certified deaths account for 22.5 per cent of total registered deaths at National level (including figures of 34 States/UTs). The Committee notes that lack of a well defined system to log the cancer deaths poses a big hurdle in the collection of accurate cancer mortality data. The Committee emphasizes that incomplete and inaccurate account of death may further lead to a poor database on the mortality data of different types of cancer. The Committee, therefore, recommends that there is an urgent need to develop a better system of reporting the causes of death so that cancer mortality can be projected in a better manner.

(Para 1.8.2 )

The Committee expresses concern over the alarming trend of increase in patients diagnosed with cancer, deaths due to cancer that is expected to rise from approximately 8 lakhs in 2018 to about 13 lakhs in 2035. The Committee notes the submission that the mortality: incidence ratio of 0.68 in India is higher than that in very high human development index (HDI) countries (0.38) and high HDI countries (0.57). Although, such disparity is because of over diagnosis in more developed countries, however, the Committee emphasizes that it could be due to the unequal distribution of and lack of access to health care resources across India.

(Para 1.8.3)

## **Major geographical variation in the incidence of cancer**

The Committee takes into account the major geographical variation in the incidence of Cancer cases and feels that the Government should encourage region based cancer research projects to understand the causation of specific cancer in a specific region and come out with the conclusion and research outcome for cancer treatment. Similarly, cancer research projects should also cover studies on differential occurrence of cancer in rural and urban areas and provide key solutions to the increasing incidence of cancer cases in rural areas.

(Para 1.9.3 )

## **CANCER PREVENTION**

The Committee recommends that the Government pays attention to low-hanging fruits by stressing the need for cancer prevention and screening. While cancer prevention measures like increasing awareness amongst masses can make the public at large more aware and allay fears regarding cancer, adequate and effectively implemented screening measures would result in early detection of potential cancer cases, thereby decreasing the load on existing health infrastructure and also saving the family/patient from financial hardships. Appreciating the importance of screening the Committee recommends the Government to formulate a nationwide policy on screening, and as in the case of Covid-19 vaccination, the Government can implement compulsory cancer screening measures on certain age groups, like 30+ age group population.

(Para 2.2.3 )

### **Vaccination against Human Papilloma Virus (HPV)**

The Committee has been given to understand that certain common cancers viz. cervical, vaginal, vulvar as well as genital warts which are mostly associated with Human Papillomavirus (HPV) infection can be prevented with vaccination. The Committee observes that vaccination for Cancer like the disease itself is associated with stigma and fear and hence it is necessary to raise awareness for both primary care physicians and patients on early warning signs/ symptoms of Cervical Cancer. The Committee feels that there is still lack of a consensus for using HPV vaccine to prevent Cervical cancer. Taking into account the fact that the vaccine has proved effective in preventing Cervical cancer in countries like Australia, the Committee recommends the Ministry to authorize few more projects to study the efficacy of the vaccine on Indian women, and if satisfactory results are achieved, the Government may consider including the HPV vaccine in the vaccination programme of India.

(Para 2.3.2)

The Committee further believes that intensive information, education and communication (IEC) activities are required to sensitize the people about the danger of the Cancer disease and the advantages associated with its early detection through screening. The Committee recommends that to increase the awareness, the Government should organize block-level camps, programmes at Schools, Colleges, universities and also start mass radio and media campaigns (like it did to eradicate TB, polio, etc) for spreading cancer awareness in the general population regarding (i) preventive care for

cancer (ii) symptoms of common cancer and reach out to the affected people at early stages in order to save the human and financial resources of the country. Additionally to give impetus to the awareness about Cancer, the Government should take following measures:

- i. Information dissemination through village panchayat members, primary health centers staffs, posters and banners in bank and post office branches. Also, local political leaders, religious leaders and other social groups should be sensitized and their help should be taken to spread awareness and motivate the population to undergo screening.
- ii. Local Cable network should also be used for creating awareness. Such networks can air awareness based programmes using local actors to sensitize people about Cancer.
- iii. School Students and the teachers should be made aware about Cancer, and then camps should be organized under NSS (National Service Scheme) where these children should increase awareness about Cancer, need for screening in nearby villages and settlements.
- iv. The Resident Medical Officers (RMOs), Ayurvedic MOs and Homeopathic MOs should also be engaged to generate awareness about the cancer prevention and importance of screening.
- v. Health workers like ASHA/Health/Anganavadi workers should be trained and provided with IEC materials so that they can interact with local population effectively.
- vi. The Government should start a help line number integrated with telemedicine (eSanjeevani-app of government) for cancer awareness, in addition to the awareness, the helpline shall be able to guide patients on next steps of care/ treatment facilities in their vicinity and how to avail the same.

(Para 2.3.3 )

The Committee notes that in India tobacco use in different forms accounts for nearly 50 % of all cancers, these are called tobacco related cancers, so these cancers are preventable. The Committee expresses its concern to note the fact that while thousands of crores are spent by both Central and State Governments on treatment of Cancer, however, the desired focus is not given to its root cause i.e. tobacco consumption. The Committee has been given to understand that majority of tobacco addicts start in their teens. Therefore, the Committee recommends the Government to focus campaign against tobacco consumption by youth and since the "quit-rate" in India is very low, the Government should formulate strategies to stop the teen-population from falling prey to the tobacco addiction.

(Para 2.3.4)

The Committee notes that another preventable cancer is Cervical cancer, which is the second most frequent cancer among women between 15 and 44 years of age with a high death ratio in India. The Committee has been given to understand that the Drugs Controller General of India (DCGI) recently granted market authorisation to Serum Institute of India (SII) to manufacture indigenously-developed India's first Quadrivalent Human Papillomavirus vaccine (qHPV) against cervical cancer.

(Para 2.3.5)

Regarding lifestyle practices that enhance risk of cancer, the Committee observes that the Government should work towards preventing obesity in youth by increasing the levels of physical activity. The Committee recommends that this can be done by two ways: (a) better urban and rural planning, making sure that physical activities are encouraged by way of dedicated jogging, walking and cycling tracks; Yoga should be promoted and made mandatory in schools for well being of children; (b) dissuade children from consuming ultra-processed foods and drinks which lack nutrients by ensuring Front of Packet Labels (FOPL) which is easily seen and understood; (c) increase in the taxes on junk food and sugary drinks which is actually creating an epidemic of obesity, especially among young children. The Committee has been given to understand that improper methods used for food preservation is one of the main reasons why the cancer incidence in the North-East India is much higher than the rest of the country. The Committee, therefore, recommends that the Government should promote better hygiene and encourage people to avoid foods (processed meat) that have been processed and preserved by employing techniques of salting, smoking or curing as consumption of even small amounts of these food increases the risk of cancer.

(Para 2.3.6)

### **Challenges in Cancer Prevention**

The Committee takes cognizance of the various challenges being faced in the prevention of Cancer and agrees with the fact that most of the people with cancer, prefer approaching the private sector, due to low trust and inadequate public cancer care services. The Committee recommends the Ministry to work actively towards bridging the trust deficit in public health institutions by improving the overall healthcare infrastructure of the public health facilities. The Committee feels that the need of the hour is to upgrade existing cancer care facilities and expand the same to the areas which have high incidence of cancer cases especially in the North Eastern Region so that the patients get access to quality and cost-effective cancer care.

(Para 2.4.1)

### **CANCER SCREENING & EARLY DETECTION**

The Committee notes that the screening of common Cancer under NPCDCS program is mostly opportunistic, which is volunteer based, and thus lacks the follow up strategy for further investigation and treatment of those who are screened positive, due to this the results may not be evaluated any further. Moreover, only three common Cancers - oral, cervical and breast are focused under the NPCDCS since inception of the program. With enough evidence with respect to increase in burden of other Cancers, the Government must consider inclusion of other prevalent cancer types under the program. The Committee further notes that while many cancers are preventable not all cancers are preventable, being age related, i.e. breast cancer, bowel cancer, prostate cancer etc. Hence strategy in these cancers is not prevention but early diagnosis through screening programs and their management. The Committee is of the opinion that there is an imminent need for a Central Government sponsored national screening programs for cancer in India.

(Para 2.5.4)

The Committee recommends that from the present policy of opportunity based screening, the Government should formulate a scheme to start a country wide

population based screening at the PHC level under the NHM (National Health Mission). The Committee is of the considered view that for screening programmes to be easily accessible, particularly for women and other vulnerable groups, they need to be decentralized to grass root level. The Committee recommends that each PHC should take up the responsibility of screening people who reside in its catchment area. The Medical Officer, Public Health Nurse, Health Assistants, and Health Workers should be encouraged to take a lead in the screening camps organized under the scheme. Furthermore, according to convenience of the PHC, one-two days in a week should be designated for Cancer Screening. The days for screening should be prominently displayed through billboards near the PHC and other locations of high population density. The Committee feels that proactive Government efforts are required to contain the growing trend of cancer. Accordingly, the Committee recommends that the Central Government in tandem with State Governments should commence Cancer mobile detection programmes with vehicles equipped with colonoscopy, mouth inspection, uterine-cervix tools & instruments, and other laboratory facilities in every district of the country. The Government must also work towards reaching the needy as has been done in Polio vaccination and start home screening for detection of breast, cervical and oral cancer. The Government should also develop mechanisms to link the screening programmes to cancer registries across the country, for better management of cases at early stages and data containing information on incidence and prevalence of cancer and related morbidities should be utilized in future cancer control programmes.

(Para 2.5.5)

The Committee feels that in order to address the issue of prevention of all sorts of Cancer, mandatory screening of people of certain age groups for example 30+ age group population may be done every year. Early detection and timely diagnosis reduces the cost of care and mortality significantly. Therefore the trumpet call is to take all the measures for mass level cancer screening. People, who avail of screening for cancer should get atleast marginal concessions in the insurance, so that provision of concession acts as an incentive for citizens to participate in the screening as per government guidelines.

(Para 2.5.6)

#### **Organization of Referral and Treatment Services**

The Committee acknowledges the detailed Operational Guidelines (OGs) for screening enlisted in "Operational Framework: Management of Common Cancers". The Committee recommends the Ministry to develop plan for the implementation of the framework. The Committee also recommends that screening programmes should be brought closer to the community by establishing the screening facilities in the PHCs and CHCs, also viable referral linkage to diagnosis and treatment centers at secondary or tertiary levels should also be ensured.

(Para 2.6.4)

#### **CANCER DIAGNOSIS**

The Committee notes that each Cancer is diagnosed with a combination of tests including advance diagnostic methodologies such as molecular biology, next-generation sequencing, Artificial Intelligence, advanced imaging, and radiation making the overall process, resource intensive and technical. The Committee recommends the DoH&FW and ICMR to set up standard diagnostics protocol and explore the inclusion of new diagnostic technology as modern technology could make the Cancer management more

precise, targeted, cost effective and efficient. The Committee is however concerned that the diagnostics procedures are very costly and due to lack of diagnostic facilities in the public hospitals, patients have to rely on private hospitals for testing where they are charged heavily. The Committee, therefore, recommends to cap diagnostic testing charges so as to give relief to the patients and this will also encourage the screened positive cases to turn up for diagnostic testing. The Committee further recommends the Ministry to do an assessment of diagnostic facilities in all District Hospitals (DHs) in the country and work towards establishing decentralized diagnostic testing network by establishing basic diagnostic facilities in all the District Hospitals (DHs) in the country, the Ministry should incorporate extensive coverage for diagnostic services under PMJAY.

(Para 2.7.6)

### **Human Resource Requirement**

The Committee appreciates the Ministry for developing a detailed "Operational Framework: Management of Common Cancers" enlisting the details of screening methods, diagnostic procedures and training requirements of the human resource involved. The Committee recommends the Ministry to develop plan for the implementation of the framework and ensure that the requisite number of healthcare personnel are appointed in PHCs, CHCs and DHs as early as possible. The Committee also recommends that the Ministry should develop certain indicators to ascertain the effectiveness and progress of the "Operational Framework" once it gets implemented. The Committee recommends adding relevant attributes/ indicators to large scale periodic surveys such as the National Family Health Survey (NFHS), National Sample Survey Organization (NSSO), District Level Household Surveys (DLHS) to assess the impact.

(Para 2.8.1)

### **Training Strategy**

The Committee observes that one major hurdle in successful early detection of cancer cases is lack of knowledge at the physician level about early signs of cancer. The Committee, therefore, strongly recommends that all Primary Care Physicians and frontline Healthcare workers to be trained for identification and detection of red flags for early diagnosis, further referral and follow up care management. A structured course including clear clinical pathways may be mandated to be taken on regular intervals. This will promote early diagnosis and treatment. The Committee recommends the Ministry to set up well-defined and established referral mechanisms so that patients are referred to the „nearest and appropriate“ diagnostic facility (including imaging, laboratory or molecular tests) for pathological confirmation and staging studies. This can help to augment capacities for early diagnosis by integration and coordination of all existing facilities in the country. The Committee recommends that to augment existing facilities, private facilities should also be empanelled to provide easy access to patients to provide free/subsidized screening/diagnostics for cancer.

(Para 2.9.2)

### **ICMR-India Cancer Research Consortium (Diagnostics):**

The Committee understands that the screening followed by diagnostic programs for cancer require the assurance of high quality treatment at affordable costs, regular follow up and accessible follow-up management as and when required. Cancer screening centres must have 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. The Committee, therefore, recommends the respective State Governments to smooth linkage between the screening facilities to diagnosis centers and subsequent treatment facilities like CHCs, District Hospitals and tertiary level hospitals.

(Para 2.11.1)

**Case Study: The National Institute of Cancer Prevention and Research, Noida.**

**NICPR's Demonstration Projects**

The Committee notes the mandate of NICPR with respect to Cancer prevention, awareness generation and research on prevention and diagnostic methodologies. The Committee notes that the institute is actively involved in studies to ascertain the prevalence of Cancer in different regions. The Committee recommends the Institute to widely publish the outcomes and findings of its studies in the public domain.

(Para 2.13.1)

The Committee takes note of the Institute's efforts in liaising with the State Health Departments to impart training to medical health providers. The Committee, in this regard, recommends the institute to improve its engagement with States so that more and more States send names of the officials who have to be trained, the institute must follow up with States which fail to send the names of the officials. The Institute must further ramp up its screening, awareness and prevention efforts by publishing more booklets and modules on prevention and screening in all the languages and distributing it through the ASHA and ANM workers. The institute should also ramp up its training activities in view of the increased future requirements for the cancer care in the country.

(Para 2.13.2)

The Committee recommends the Institute to make SWOT (Strength, Weakness, Opportunity & Threats) analysis in its functioning and chalk out "Key Concern Areas" of management of the Institute so as to give impetus to achievement of its mission objective and improve the professional pursuit.

(Para 2.13.3)

**National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Disease & Stroke (NPCDCS)**

The Committee observes that the merger of National Cancer Control Programme (NCCP) into the NPCDCS has reduced the focus and proper handling of cancer screening. The Committee notes that India lacks a robust policy on cancer control in India and there is an urgent need to strengthen the screening and early detection & diagnosis infrastructure in the country. The Committee, therefore, is of the opinion that cancer must be dealt with separately and must not be grouped under other lifestyle diseases. The Committee accordingly recommends the Ministry to devise a targeted plan for tackling cancer before it blows out of proportion and consume a major part of human and financial resources of the country.

(Para 3.3.6)

The Committee is given to understand that there is a definite need for systematic data collection and aggregation, evaluating patterns of care, and health technology assessment to channelize scarce healthcare resources appropriately. The Committee, therefore, feels that systematic data collection and aggregation can optimally utilize the healthcare resources.

(Para 3.3.7)

The Committee in its 134<sup>th</sup> Report on Demands for Grants 2022-21 of the Department of Health and Family Welfare had also noted that Rs. 175 crore was approved in BE 2021-22 for NPCDS which was later reduced to Rs. 146.88 crore. The Committee believes that the allocation of funds should also be considerably increased for tackling cancer and other lifestyle diseases. The Committee reiterates that the Ministry must make a realistic requirement of funds to support the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke. The Committee would also recommend the Ministry to assess the continued relevance of the Scheme and the progress made towards achieving the envisaged objectives under the Scheme.

(Para 3.3.8)

The Committee would also like to be apprised of SWOT analysis of the Scheme and recommends the Government to work upon the weakness and threats of the Scheme and take advantage of strength and opportunities of the Scheme for better result.

(Para 3.3.9)

#### **Functioning of Non Communicable Disease (NCD) Cells**

The Committee is disappointed to note that only 1.2% of the population is covered in population based cancer screening programme. The Committee notes that the Non Communicable Disease Cells could have been optimally utilized for screening of cancer patients, however, the NCD Clinics have failed to emerge as centers of first line screening for cancer patients. The Committee strongly feels that early diagnosis of cancer is the best chance for successful treatment. With delay in detection of cancer, the cost of treatment and care also increases as associated risks become graver. The Committee recommends the Ministry to ensure that the NCD Clinics are made fully functional and robust screening of common cancer is done in the clinics. The Committee also recommends the Ministry to provide adequate training to the health care professionals at the NCD Clinics/ Primary Health Centre/ Community Health Centre for the screening of common Cancer.

(Para 3.4.2)

The Committee observes that the prevalence of NCDs have been on a rise, however, the Scheme has failed to achieve the desired outcomes. The Committee is also of the opinion that there is a need to generate awareness among the general public regarding the regular screening of cancer in the NCD clinics or some other private centers. The Committee recommends the Ministry to conduct more awareness camps and work on capacity building, patient advocacy, health promotion, etc. The Committee further recommends the Ministry to put in place a mechanism wherein probable cancer positive individuals are compulsorily referred to the cancer centers where they undergo further elaborate tests. The treatment must commence at the earliest so that the

survival rates are increased. The success of the National Cancer Control Plan will only be ensured when early cancer detection is followed by early treatment. The Committee observes that developing an effective preventive strategy for tackling NCDs need a multi-sectoral approach.

(Para 3.4.3)

### **Tertiary Care for Cancer**

The Committee notes that the Cabinet Committee on Economic Affairs (CCEA) had approved the Scheme of "Strengthening of Tertiary Care Cancer Facilities" in 2013 which was aimed to enhance the tertiary care facilities in the country. The Committee however, notes that the completion of all the 19 SCIs and 20 TCCCs has been considerably delayed and is expected to be completed by 31.03.2024. The Committee further notes that the States are the main implementing agencies under the Scheme and both the States and the Centre contribute to the Scheme. The Committee is of the view that the States and the Centre shall work in tandem to complete all the SCIs and TCCCs within the revised schedule. The Committee accordingly recommends the Ministry to hold regular review meetings with the States and ensure the successful completion of all the 19 State Cancer institute (SCI) and 20 Tertiary Cancer Care Centre (TCCC).

(Para 3.5.4)

### **Pradhan Mantri Swasthya Suraksha Yojana (PMSSY)**

The Committee observes that among the 22 new AIIMS, presently cancer treatment facility is available only in 6 AIIMS i.e. Bhopal, Bhubaneswar, Jodhpur, Patna, Raipur and Rishikesh. The Committee further finds that Cancer treatment facilities have also been created/ planned in 13 State Government Medical Colleges which have been taken up for up-gradation under PMSSY. The Committee notes that the main objective of PMSSY was to correct regional imbalances in the availability of affordable/reliable tertiary healthcare services. With an increase in cancer incidences across the country, it is all the more necessary to strengthen the tertiary healthcare services especially the cancer treatment facilities in the hospitals/Institutes. The Committee accordingly recommends the Ministry to take measures to expedite the setting up of cancer treatment facilities in AIIMS like Institutions and Government Medical Colleges under PMSSY. The Committee strongly recommends the Ministry to ensure that the required manpower is available in these Institutes and all the Departments of Oncology are made functional within a stipulated time frame.

(Para 3.6.3)

The Committee believes that timely diagnosis of cancer is crucial for providing comprehensive cancer care, however, the Government Medical Colleges and Hospitals at district level lack the infrastructure and facilities for accurate cancer diagnosis. The Committee strongly recommends that under the GMC upgradation component of the PMSSY, the Ministry must ensure that screening and diagnostic tests especially for common cancer are present in the District Hospitals. The Ministry of Health and Family Welfare must also ensure that adequate number of healthcare workforce is present in the GMCs that are well trained in cancer screening and diagnosis.

(Para 3.6.4)

## **National Cancer Grid**

**The Committee commends the Department of Atomic Energy for creating the National Cancer Grid and believes that the DAE along with the Ministry of Health and Family Welfare must make consistent efforts to bring in a uniform criterion for prevention, early diagnosis, treatment protocol and follow up of cancer patients. The Committee would also like the Ministry of Health and Family Welfare to explore a process of audit and peer review of the Cancer Centres and monitor the progress of Cancer Centres under the National Cancer Grid in tandem with the Department of Atomic Energy.**

**(Para 3.7.7)**

**The Committee notes that there is wide disparity in the incidence and mortality of cancer across the different regions of the country. The Committee notes that there is huge variation in the treatment procedure followed and the standards of cancer diagnosis across the country. The Committee believes that uniform high standards of cancer care must be provided throughout the country. The Government machinery must ensure that the Cancer Centres across the country follow a common standard management guideline for cancer care. The Committee further recommends the Ministry of Health and Family Welfare to bring in a mechanism to capture the data of each cancer patient and assess the pattern of cancer across the country.**

**(Para 3.7.8)**

**The Committee accordingly recommends the Ministry to periodically modify the Guidelines as per new researches and studies on cancer. The Committee further recommends that the Government should make efforts to strengthen the network of Cancer Centres and include more Cancer Centres under the National Cancer Grid. The Committee hopes that the Cancer Centres across the country are able to benefit from the State of the art Cancer Centres under the NCG. The Committee would also like the Government to explore the idea of establishing a mentor institute in each region which facilitates training, cancer research and more collaboration among the institutes of the region.**

**(Para 3.7.9)**

## **Hub and Spoke Model of Cancer Care**

**The Committee notes that cancer cases in India are diagnosed at a later stage which is a major cause of high mortality to incidence ratio and increase in cancer care expenditure. The Committee believes that a strong network of cancer care centres across the country would facilitate early diagnosis of cancer cases and greatly reduce the burden of cancer cases in India. The Hub and Spoke Model is an efficient distribution model of providing comprehensive cancer care by creation of hubs and spokes in all the States of the country. The Committee notes that TMC has worked in close contact with the State Governments to create hubs and spokes in States. The Committee believes that such collaborations will enable in further strengthening the cancer care infrastructure along with knowledge, skill and resource sharing. The Committee appreciates the work done by TMC and DAE and advocates the need for establishing government funded hub and spoke model of cancer care across States. The Committee further believes that ensuring adequate human resource in Cancer centers under the hub and spoke model is also crucial for complete operationalization of the Centers.**

(Para 3.8.5)

The Committee agrees with the Department of Atomic Energy that there is a need to identify region wise cancer burden and common types of cancer in different regions. The Committee is of the opinion that a correct assessment of the cancer burden would facilitate formulation of an effective strategy for creation of hubs and spokes in the country. The Committee recommends the Ministry of Health and Family Welfare to work in close collaboration with the Department of Atomic Energy to decide a timeline for implementing the hub and spoke model in each State. The Committee urges upon the Government to ensure that the existing SCI/TCCCs are upgraded to hubs and spokes depending on their existing infrastructure and capabilities.

(Para 3.8.6)

The Committee is of the considered view that the Union Government should take a lead in setting up of new cancer centres in a phased manner and ensure that the State Governments must provide land and other necessary approvals without any delay to the projects. With such an apex Institute like TMC on board, the Committee expects the State Governments to benefit from its experiences and technical expertise of TMC. The State Governments must take a proactive approach in identifying the land and sending the necessary proposals to TMC without any delay and hassels.

(Para 3.8.7)

The Committee also notes that the most common form of treatment is radiotherapy and patients continue to attend hospitals for many days. The Government must ensure that guest houses are established near the Cancer Centers where the patients can stay at subsidized costs. Making adequate arrangements for patients stay will further reduce the cost of cancer treatment. The Committee, accordingly, recommends the Ministry to make facilities for subsidized or free accommodation in each of the hubs and spokes. This will ensure that the out-station patients can complete the treatment without being forced to spend on accommodation in hotels or hostels in the city.

(Para 3.8.8)

#### **Pradhan Mantri Jan Arogya Yojana (PM-JAY)**

The Committee finds that AB-PMJAY is the flagship scheme of the Government that aims to provide comprehensive healthcare services to the beneficiaries, nevertheless, lack of awareness and poor screening services have been major challenges in providing cancer care under the Scheme. The Committee observes that PMJAY provides support for medical treatment for underprivileged families, however, the Committee believes that the Scheme should be extended to include diagnostic tests and other services. The Committee notes that initial investigations can be very expensive and is often the reason that leads to delay in treatment. The Committee accordingly, recommends the Ministry to include various types of necessary diagnostic tests under the Scheme so that timely detection of cancer can improve the cancer mortality rate.

(Para 3.9.11)

The Committee takes into account that the Scheme was aimed at reducing catastrophic expenditure for hospitalizations so that entitled families do not face any financial hardship. The Committee observes that doctors' entire prescription as well as all forms of latest therapy is not covered under Ayushman Bharat which leads to compromise in quality of treatment. The Committee, accordingly, recommends the

Ministry to update the list of medication regularly in line with advancement in technology and treatment procedures. The Committee agrees with the view of Pfizer and recommends the Ministry of Health and Family Welfare to explore innovative funding models for inclusion of more targeted oncology treatments under AB-PMJAY.

(Para 3.9.12)

The Committee notes that Oncology has been one of the most used tertiary specialities in PMJAY which reaffirms the urgent need to review cancer treatment packages and expand the cancer services under the Scheme. The Committee, therefore, appreciates the partnering of NHA with NCG which will incorporate quality parameters along with empanelling of more NCG member organization under PMJAY. The Committee, in this regard, recommends the Ministry to include oral therapies that have already been listed as essential (or mandatory) or preferred (cost effective with evidence of efficacy) by National Cancer Grid under AB-PMJAY. The Committee advises the Ministry of Health and Family Welfare to review the existing cancer treatment packages and standard treatments covered under the Scheme.

(Para 3.9.13)

The Committee believes that integration of NHA with NCG will facilitate linking of cancer registry with repository of data under the PMJAY Scheme. Such measure will not only improve the accuracy of the cancer registry but also ensure a smooth referral and follow up system. The Committee believes that early screening and diagnosis of cancer is crucial for effective treatment of the cancer.

(Para 3.9.14)

The Committee notes that SECC data is the criteria for the beneficiaries under the PMJAY and some States have expanded the list of entitled beneficiaries under similar schemes. The Committee desired that SECC data not only need to be updated to broad base the scheme by including the middle class as beneficiaries but PMJAY and other similar schemes as operational in various states should also aim at to provide financial assurance to patients suffering from cancer and other diseases.

(Para 3.9.15)

The Committee believes that a mandatory screening of beneficiaries of Government Health Scheme for common cancers will help increase the scope of the screening program. The Committee, in this connection, recommends the Ministry to conduct a mandatory annual cancer screening checkup for all Ayushman Bharat beneficiaries which will facilitate early cancer diagnosis. The Committee reiterates that such exchange of patient care information will not only help in better cancer management but also a more accurate cancer database.

(Para 3.9.16)

#### **Important Institutions for Cancer-Patient Care**

##### **Chittaranjan National Cancer Institute, Kolkata**

The Committee notes that CNCI has been providing healthcare services to the masses, however, there is delay in the recruitment of healthcare professionals in the Institute. The Committee is of the opinion that shortage of staff in both the campuses of the Institutes may lead to many Departments being non-functional at CNCI. The Committee, accordingly, recommends the Ministry of Health and Family Welfare to

ensure that adequate staff is made available at the Institute vis-à-vis sanctioned posts on priority.

(Para 3.10.4)

The Committee further notes that CNCI is one of the 25 Regional Cancer Centres in India and was envisaged as a cutting-edge cancer research centre, however, the Institute must take effective steps to expand its activities in basic and clinical research so as to draw conclusion out of translational cancer research.

(Para 3.10.5)

The Committee observes that Chittaranjan National Cancer Institute, Kolkata has started a 30 bedded palliative care or hospice. The Committee agrees with the suggestion of the Director, CNCI that there is need of more Government support on palliative care and hospice. The Committee recommends the Ministry to give more thrust on Palliative care and provide support on Government-aided homecare support. The Committee accordingly recommends the Ministry to make continuous efforts for development of CNCI into a referral centre for Palliative care to all cancer care Institutes of Eastern India.

(Para 3.10.6)

The Committee further recommends the Ministry to incorporate telemedicine services from the Primary Health Centers to the District/ Sub-divisional hospitals to the referral hospitals. The Committee is of the opinion that proper linkages between the PHC and Cancer Care Centres is missing. As a result, many of the referred people skip receiving treatment. The Committee, therefore, recommends the Ministry to strengthen the existing referral mechanism which will not only ensure a robust treatment plan but also facilitate better documentation of cancer related data.

(Para 3.10.7)

#### *Case Study : Tata Memorial Centre*

The Committee commends the Tata Memorial Centre for providing outstanding service through evidence based practice of oncology and guiding the National Policy and strategy for cancer care. The Committee is assured that comprehensive cancer centers under the hub and spoke model will facilitate decentralization of cancer care. The Committee appreciates the expansion of TMC to seven hospitals located in Varanasi (two), Guwahati, Sangrur, Visakhapatnam, New Chandigarh and Muzaffarpur. The Committee accordingly recommends the Ministry of Health and Family Welfare and Department of Atomic Energy to indentify the probable hubs and spokes and expedite the creation of hubs and spoke under the guidance of TMC.

(Para 3.11.7)

The Committee appreciates the TMC model of revenue generation that reduces the dependence on the Government for funds. The Committee notes that nearly 60% patients receive highly subsidized or almost free treatment and rest are private patients who pay for their care. Cancer treatment is financially draining and needs specific intervention on the part of the Government. The Committee accordingly believes that the Government may explore replicating the TMC model of revenue generation in other Cancer Institutes.

(Para 3.11.8)

The Committee finds that TMC receives financial support from various government and non - government organizations to look after the needs of accommodation of the poor cancer patients. Taking a clue from the TMC Model, the Committee recommends the other Institutes to explore mobilizing the finances through philanthropic sources including Corporate Social Responsibility (CSR).

(Para 3.11.9)

The Committee believes that the costs for cancer treatment can be further brought down by group negotiation for construction activities, equipment, drugs, and consumables. The Committee appreciates the efforts of TMC in this regard and recommends TMC to continue sharing its rate contract with other State Governments who can avail the benefits of the negotiated prices by TMC.

(Para 3.11.10)

*National Cancer Institute, Jhajjar*

The Committee notes that NCI-Jhajjar has been envisaged as an apex cancer treatment and research facility by the Ministry, however, the Institute lacks the facilities of in-house pathology, microbiology & molecular oncology investigations. The Committee strongly recommends the Ministry to make these services functional in NCI at the earliest and reduce its dependence on AIIMS, New Delhi.

(Para 3.12.9)

The Committee finds that there is shortage of healthcare workforce in the Institute which has a grave impact on the functioning of the Institute. The Committee accordingly recommends the Government to ensure that adequate number of doctors and specialists are made available along with the administrative staff. The Ministry must expedite the recruitment for residents, senior residents, Senior Nursing Officers, ANS, DNS, Physiotherapists, Pharmacists as well as the other administrative staff.

(Para 3.12.10)

The Committee takes into consideration the submission of the Ministry that there is adequate space & infrastructure available at NCI-Jhajjar and majority of cancer services currently offered at AIIMS, New Delhi can be shifted to NCI-Jhajjar. The Committee, accordingly, recommends the Ministry of Health and Family Welfare to explore transferring certain facilities at NCI so that the waiting list at AIIMS Delhi is reduced.

(Para 3.12.11)

The Committee notes that the transportation facility to the Institute is very poor and it takes a lot of time for the people to go from main campus to the NCI. The Committee, accordingly, recommends the Ministry to make proper transport arrangements and ensure proper connectivity around the area.

(Para 3.12.12)

The Committee believes for ensuring the recruitment of young talent in NCI-Jhajjar, the Ministry will have to take effective measures and develop adequate social infrastructure like schools, shopping areas, recreation space, parks, etc. around NCI-Jhajjar. The area will have to be made more habitable and attractive so that medical practitioners willingly join the Institute. The Committee accordingly recommends the

Ministry of Health and Family Welfare to develop the infrastructure around NCI in coordination with the State Government and also start certain financial incentive package for the staff recruited in NCI.

(Para 3.12.13)

The Committee draws the attention of the Ministry of Health and Family Welfare to ensure that all the weaknesses related to the working of NCI are overcome and specific interventions are made to ensure proper operationalization of the Institute by adopting guiding principles of the management by objectives.

(Para 3.12.14)

The Committee recommends the Ministry to devise a rating mechanism for the hospitals on the quality of care, cost-effectiveness of the treatment provided and other relevant parameters. The Committee further believes that an assessment of various treatment outcomes out of all the available treatment options in Modern Medicine is also important to improve the Standard Treatment Protocol and patient outcome. The Committee accordingly recommends the Ministry to conduct long term research on long term outcomes and follow ups on impact of treatment on patients, especially from the effect of surgery, effect of chemotherapy and effect of radiation therapy on patients.

(Para 3.12.15)

#### *Regional Cancer Centre (RCC), RIMS, Manipur*

The Committee notes that Manipur has one of the highest incidences of cancer in the North Eastern area. M.D. in radiation oncology was started in 2001 in RIMS Manipur and the Institute was upgraded to Regional Cancer Centre in 2006. The Institute was envisaged as a specialized cancer centre, however, the Committee observes that RIMS has very limited facility in terms of infrastructure and trained manpower. Cancer Patients from the North Eastern Region have to go to other parts of the country for cancer treatment.

(Para 3.13.6)

The Committee notes that irrespective of RIMS Manipur serving as a RCC, Departments of Surgical Oncology, Medical Oncology and Nuclear Medicine are non-functional in RIMS. The Committee also observes that RIMS had applied for up gradation to Tertiary Cancer Care Centre in 2014 and the approval has not yet been received. The Committee is appalled to note that the Institute does not even have the facilities of PET scan. The Committee strongly recommends the Ministry to ensure that the Institute starts functioning as a Tertiary Cancer Care Centre and various Departments of Oncology are made functional in the Institute along with the desired number of human resources.

(Para 3.13.7)

The Committee believes that for strengthening of Institutional arrangement, the key concern areas as highlighted by RIMS must be adequately addressed. The Committee in its 126<sup>th</sup> Report had also examined the status of vacancies in RIMS and noted that the patient load has increased many fold in the last 20 years. However, the sanctioned strength of faculty has remained the same. The Committee reiterates that the Ministry must take concrete steps for creation of new Posts and expedite the recruitment process to fill up the vacant posts.

(Para 3.13.8)

## **Changes needed in the Institutional Framework**

### ***Need for a Centralised Public Health Research Institute***

The Committee observes that India has an extensive network of Public health Institutions from the Health Wellness Centres to the Tertiary care Centres. However, there is a big scope for upgradation and the delivery of health care services at these Centres. The Committee further notes that ICMR is the National apex Research body that conducts research on various public health issues. The Committee however feels that there is a great need to utilise the outcomes of the research findings by ICMR and other Research Bodies in institutionalizing a better framework for cancer care and its management. The Committee notes that the States lack the Technical expertise to formulate specific cancer care policies in the State. The Committee finds that the rates of cancer incidences are different across States. Some form of cancer is more prominent in some regions whereas some States report lower incidences of the same cancer. The Committee strongly feels that a one size fits all approach cannot be adopted if the cancer incidence is to be controlled. The Committee therefore strongly recommends the Ministry to ensure that the National Research Bodies to the likes of ICMR collaborate with the States in designing State specific institutional framework across the country.

(Para 3.14.1)

### ***Region-wise equitable distribution of Government-run Cancer Centres***

The Committee is of the view that there is an urgent need to strengthen the existing cancer centres across the States/UTs on priority basis. The Government, through its various initiatives such as the National Cancer Grid, is working towards providing uniform cancer care across the country. The Committee however feels there is a need to expand the network of cancer centres in the country. It is a well established fact that cancer care is financially draining on the patient's family and drives families to poverty. The Committee expresses its concern that there are many regions which remain deprived of modern cancer care. The Committee accordingly believes that the Government must establish additional Government cancer centers so that affordable high quality cancer services are provided to the general public. The Committee reiterates that the Government must ensure the completion of the envisaged State Cancer Institute (SCT) and Tertiary Cancer Care Centre (TCCC). The Committee commends the partnership between Tata Memorial Centre and State Governments and recommends the Ministry to encourage such collaboration across the country. The Governments must explore public-private partnerships for establishing more Cancer Care Centers and adopt best practices and provide standardized treatment protocol in these Centers.

(Para 3.14.2)

The Committee also recommends the Ministry to create a platform where these Institutions can interact and learn from the best practices followed in each Institute on the novel initiatives taken for making cancer care affordable. Such a platform will also facilitate a comprehensive assessment of the affordability as well as the efficacy of the treatment protocols.

(Para 3.14.3)

### ***Price negotiation***

The Committee takes into account that anti cancer drugs as well as equipments are very expensive and the Cancer Centers would find it difficult to negotiate competitive prices with equipment manufacturers and the pharmaceutical industry. The Committee has also been informed that the exploiting the volumes of individual cancer centres, the NCG has negotiated with pharmaceutical companies for high value cancer drugs. By aggregating the demand from many centres, the NCG worked on a solution wherein “price discovery” of commonly used, high-value items are negotiated with industry, thereby passing on the benefits to member centres and onwards to patients. Using transparent policies for tendering and a web-enabled e-tendering platform, this initiative has brought down current costs of cancer care significantly (average of 55% discount on MRP) while maintaining the quality of drugs.

(Para 3.14.4)

The Committee believes that Group negotiation for cancer drugs would facilitate better price for the anti cancer drugs by increasing the bargaining power. The Committee accordingly recommends the Government to take measures to encourage such group negotiation for cancer drugs through a transparent central tendering platform. The Committee notes that such group negotiations by TMC have led to a 20 to 80 % discount on cancer drugs. The Committee further recommends the Government to extend such price negotiation to equipment & consumables also.

(Para 3.14.5)

#### *Human Resource Forecasting & Planning*

The Committee expresses concern over the lack of adequate manpower to make the cancer centres fully operational. In the absence of specialized healthcare force, many super specialities remain defunct even after the establishment of the physical infrastructure. The Committee, accordingly, recommends the Ministry of Health and Family Welfare to take effective measures to fill the vacant posts *vis-à-vis* the sanctioned strength in these Cancer Care Units. To avoid such delays in making the centres fully operational, the Ministry must make manpower provision at the time of sanctioning a project. The Committee is of the view that the State Governments must also play an active role in ensuring that the manpower in State-run Cancer Institutes is adequate. The Committee observes that very few institutions conduct technical courses that produce paramedics and technicians that can take care of increasing load of cancer patients. The Committee, therefore, recommends the Ministry to increase such courses as the trained manpower is fundamental to providing value-added-services to the patients which will help improve their quality of life.

(Para 3.14.6)

#### *Inadequate Insurance Coverage*

The Committee notes that insurance companies bank on maximization of profit and all cancer treatments are not covered in the health insurance scheme. The Committee further notes that as per current IRDA regulations, most cancer survivors cannot avail of health insurance even for non-cancer related ailments. It has been brought to the notice of the Committee that many cancer survivors were not able to get insurance cover during the COVID pandemic. The Committee accordingly recommends the Ministry to take up and pursue vigorously with the IRDA to revise the insurance regulations to ensure that the cancer patients are not denied insurance benefits.

(Para 3.14.6)

The Committee further notes that innovative health insurance packages are required for ensuring adequate financial coverage for cancer treatment. Various stakeholders have also highlighted on the need for inclusion of middle class in Government Health Schemes especially for Cancer treatment and rare diseases that necessitates high financial expenditure. The Committee notes that the middle class remain out of the ambit of Health Insurance Schemes such as AB-PMJAY and bear the expenses from their own pocket. The Committee accordingly recommends the Ministry of Health and Family Welfare to examine in the right earnest and expand the list of beneficiaries under AB-PMJAY so that middle class can also avail free treatment for critical illness such as cancer. This can go a long way in saving the families of cancer patients of middle class from going into penury.

(Para 3.14.7)

#### *Need for focused approach to Pediatric cancer*

The Committee is deeply concerned about the anticipated increase in the number of pediatric cancer patients. The Committee feels that these young patients need all out support in terms of physical as well as financial resources from the State Government and Central Government to undergo quality cancer care treatment. The Committee notes that early diagnosis of pediatric cancer can greatly increase the chances of the success of treatment. The Committee accordingly recommends that the PHC must have trained health care professionals for early cancer detection and screening and be sensitive while handling children likely to be suffering from cancer. The Committee desires the Ministry to ensure that special insurance package for pediatric cancer covers the entire cost of treatment of the child suffering from cancer or even explore the possibility of including all children suffering from cancer under the Ayushman Bharat Scheme. Further the health personnel need to be trained/sensitized with respect to compassionate and quality care of these children.

(Para 3.14.11)

The Committee observes that Home Away from Home facilities are not classified under Nursing Homes, clinics, Dharmshalas or hostels. The Committee is of the view that recognizing HAH as a separate category will help in the establishment of many such homes and ensure that the facilities operate under appropriate regulatory and legal framework. The Committee accordingly recommends the Ministry to make necessary changes and provide recognition to Home Away from Homes as a separate category.

(Para 3.14.12)

The Committee notes that with the ever increasing burden of cancer in the country, there is an urgent need to review and upgrade the institutional framework for cancer care and management in the country. The Committee observes that despite Health being a State subject, the larger responsibility lies with the Union Government for formulating different Health Policies and National Level Programs and Schemes. The Committee further notes that the Central Government with greater pool of financial resources and stronger technical support system is better equipped to ensure robust implementation of the National Health Programs.

(Para 3.14.13)

### **Strengthening the Institutional arrangement**

The Committee accordingly recommends the Ministry to strengthen every District hospital with Oncology Wing and conduct more awareness programme on utilization of central financial assistance to public & doctors for cancer treatment. The Ministry must also ensure that more cancer patient accommodation and transportation centres in every district are opened. The Ministry must also conduct specific programs for increased awareness among public and health workers about certified generic anti cancer drugs.

(Para 3.15.1)

The Committee is of the opinion that Public Health Programmes aimed at Cancer Control are crucial for improving the cancer burden in the country. A National Cancer Control Plan that is aimed at adopting evidence based strategies for cancer prevention, early diagnosis, treatment and palliative care and implementing the National Cancer Policy across the States forms the keystone in developing the desired Institutional Framework for Cancer Care and Management.

(Para 3.15.2)

### **National Pharmaceutical Pricing Authority (NPPA)**

The Committee observes that 16% margin for retailers in determining prices of the medicine under National List of Essential Medicines (NLEM) are too high as the same must have bearing on the price of the life saving medicines. The Committee is not in agreement with the argument of the Secretary, the Department of Pharmaceuticals that since a margin of 10 to 15% is provided in Government contracts or other line of business, therefore, 16% retailers margin stands rationale. The analogy between the retailers 16% margin and the profit margin of 10 to 15% margin in Government contracts or other line of business is absolute and out of context as the Government while providing healthcare services to the cancer patient should not be guided by the profit motive as in the case of the other business line. Being a welfare state, the Committee urges upon the Government to rationalize the retailers 16% margin in the interest of the patients who are struggling for their life. In case it is not possible to reduce retailers margin Government can subsidy to retailers or consumers.

(Para 4.2.10)

The Committee observes that 10% annual increment in the price of the non-scheduled drugs is allowed to the manufacturer that gives undue liberty to the manufacturer to enhance the price of the non-scheduled drugs. The Committee, while taking into account the submission of the Secretary, the Department of Pharmaceutical, that over a period of about 8 years or so the actual price increase in the drugs had been only between 2 to 4%, recommends the Government to rationalize the annual limit of 10% increment to 5% annual increment in order to rescue the poor cancer patients and their family from the dipping into scourge of poverty. The Committee recalls the submission of the Secretary, the Department of Pharmaceuticals that due to market competitive pressure the actual price increase is rarely 10%, however, it is not to say that each manufacturer keeps the price of the drug below 10% and it is also not to say that every drug utilizes the entire 10% ceiling. The Committee, accordingly recommends the Government not to allow sweeping 10% annual increment ceiling,

thereby giving the manufacturer the undue scope for "Profit Motive engineering /mongering" for skyrocketing the price of the life saving anti cancer drugs and thus compelling the patient's pressure on out of pocket expenditure thereby pushing them below the poverty line. The Committee, therefore, recommends the Government to have better approach/mechanism of regulation of anti cancer formulation/drugs.

(Para 4.2.14)

**Revision of Ceiling/Retail Price under Para 19 of DPCO, 2013: (Trade Margin Rationalization Approach)**

The Committee expresses its concern over the determination of price of the medicine under Para 19 of DPCO 2013 through Trade Margin Rationalization Approach where NPPA caps the Trade Margin at 30% of MRP of Anti Cancer Non-Scheduled Formulation. It is being pleaded that 30% margin as taken in TMR approach is the margin for both the distributor and the retailer still the 30% Trade Margin under TMR mechanism appears to be mammoth price increasing factor of life saving anti cancer medicine. The Committee, therefore, persuades the Government to explore the scope for reducing trade margin under TMR mechanism of determining the price of anti cancer formulation to a rationale level in order to make cancer treatment more affordable and thus protect the patient from dwindling into financial hardship.

(Para 4.2.17)

### **Affordable Medicines and Reliable Implants for Treatment (AMRIT)**

The Committee appreciates the provision of AMRIT Scheme for ensuring affordable life saving cancer, cardiac drugs and medical disposables. The Committee hopes that the initiative under AMRIT will offer affordable drugs and medical implants at the ground level and will ease the burden of cancer patient, especially the underserved, in meeting the cost of drugs. The Committee desires that the implementing agency of AMRIT Scheme i.e. HLL Lifecare Limited should genuinely strive to the goal of the scheme in ensuring that no patient is deprived of life saving and other drugs for reasons of unaffordability. The Committee also recommends that HLL should open the AMRIT outlets in remote village areas, urban slums and tribal areas to ensure the achievement of target of the AMRIT Scheme.

(Para 4.2.19)

### **Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)**

The Committee finds in the PMBJP Scheme that there is a word called 'Divyang' which is a sanskrit word. The Ministry of Social Welfare has urged upon to replace the word 'Divyang' with the word 'Physically Challenged or Differently Abled Person' as the word 'Divyang' is not understood to many. The Ministry of Social Welfare has sent a directive to the Ministry of Railways to replace the word 'Divyang' in IRCTC forms with english words. The Committee, therefore, recommends the Department of Pharmaceuticals to replace the word 'Divyang' with the word 'Physically Challenged or Differently Abled Person'.

(Para 4.2.23)

The Committee appreciates the efforts of Pharmaceutical and Medical Devices Bureau of India (PMBI) in implementing Pradhan Mantri Jan Aushadhi Pariyojana (PM-BJP) that intends to provide quality generic medicines at affordable costs through 8700 Jan Aushadhi Kendras. The Committee is of the view that PMBI should not only intend to operate Jan Aushadhi Kendras in all the 739 districts of the Country but incorporate into its strategy to open the Jan Aushadhi Kendras at the Block Level to ensure the accessibility of affordable and accessibility of cancer medicines to the patient at the door step. The Committee hopes that the Department of Pharmaceuticals would achieve the target of opening of 9300 Jan Aushadhi Kendras during current financial year. The Committee further recommends the Government to ensure that prescribed quality anti-cancer formulation drugs are available at the Jan Aushadhi Kendras all the time or made available within reasonable time.

(Para 4.2.26)

The Committee is of the view that under cooperative federalism institution arrangement of cancer treatment should be well knitted & integrated with coordinated structure and functional equilibrium were the vision of cancer treatment at affordable cost flow from primary health centre at the block level to the tertiary level of cancer care i.e. a network of basic to complex form/procedure of cancer treatment.

(Para 4.2.27)

The Committee appreciates the supply chain arrangement made by the Department of Pharmaceuticals, however, it is expected that the structural arrangement of supply chain management must have adequate functional operational mechanism to have the robust management for ensuring availability of medicine in all the PM Jan Aushdi Kendras.

### **Cancer Care Pathway Limits**

The Committee understands that Cancer care delivery in developing nations has always posed big questions around accessibility and affordability for most of its population. Access to the right doctors, facilities, treatment, and medication in a timely manner is limited to a few metro cities and thus, large parts of the country lack access to quality healthcare services. The Committee, therefore, recommends the Government for making policy for decentralization of cancer care facilities and treatment from metro cities to class I and II cities.

(Para 4.4.1)

The Committee takes into account that efficient delivery of cancer care is further challenged by regional disparity, marked socio-economic diversity, gaps in knowledge, health seeking behavior of the public combined with resource and infrastructure constraints. Approximately 80% of the cancer patients seek medical attention in advanced stages of disease that contributes to India's very high mortality-incidence ratio of 0.68 which is substantially higher than that of high-income countries (HICs) (0.38). The Committee, therefore, recommends the Government to take these facts into consideration while chalking out strategy to combat the menace of higher incidence of cancer.

(Para 4.4.2)

The Committee finds that the public tertiary level hospitals available across India, that provide cancer treatment, are less than 50 in comparison to the private facilities which are more than 200 in number across India. That clearly states that the infrastructure for cancer treatment in India has been tapped more deeply by private facilities than the Government facilities. Therefore, with incremental annual prevalence of approximately 14 lakhs cancer diseases in India, the burden of cancer patients on 250 health facilities has led to an unmet need or demand-supply/service delivery gap for cancer care in India. The Committee is of the considered view that there is an urgent need to expand the network of Government funded cancer treatment infrastructure to take care of increasing incidence of registered cancer patient.

(Para 4.4.3)

### **Cost of Cancer Treatment**

The Committee understands that the cost of cancer treatment is not only the price of the medicine but the cost of healthcare for any patient in the country includes a variety of charges viz. doctor consultation and nursing fee, room charge, pathological and maintenance charges thereby increasing the overall cost of the treatment. The Committee finds that Government is providing subsidized food, heavily subsidized power, however, inaccessible and increasing cost of cancer treatment is a matter of concern for the Committee, as not only the patient but the whole family undergoes tremendous psychological and economic pressure in bearing the cost of the treatment and sailing through troubled phase of life. The Committee, therefore, considers it pertinent, on the part of the Government, to take suitable measures not only for

**regulation of medicines having focus on reducing the cost of the medicine but to provide subsidized healthcare by regulating the cost of diagnostic and treatment kits and service charges for various components of healthcare rendered not only in Government Hospitals but also in the private hospitals.**

**(Para 4.5.2)**

**The Committee takes into consideration the high cost of radio therapy resulting into unaffordable cancer treatment. The Committee is in agreement with the argument of Secretary, the Department of Pharmaceuticals that NPPA is mandated only to control drug charges through DPCO and not the service charge because radio therapy service has not been declared an essential commodity/service under the Essential Commodities Act-1955 or by NLEM. The Committee, therefore, recommends the Government to examine as to the types of services that should be regulated in terms of price and therefore be made provision of the Essential Commodities Act-1955. The Committee hopes that the Ministry of Health & Family Welfare would take the matter on board for final decision.**

**(Para 4.5.3)**

#### **Poor availability of radiation machines in the Government Hospitals**

**The Committee notes that lack of adequate number of equipments in the hospital increases the waiting period for treatment. During the course of the examination of the subject, the Committee noted that the country imports radiotherapy machines from other countries and there is gross shortage of radiotherapy machines in the medical colleges. The Committee further observes that the cost of radiotherapy is very high in private sector largely because of the fact that radio therapy machines are not manufactured in India. The Committee accordingly recommends the Ministry to work on a mechanism under which either the machines are assembled in the country or are indigenously manufactured in the country. The Committee further strongly recommends the Ministry to ensure that radiotherapy machines are made available in the Hospitals/Medical Colleges that have Radiation Oncology Department.**

**(Para 4.6.2)**

**The Committee notes that the Bhabhatron-II TAW Cobalt-60 Teletherapy machine is fully indigenous unit and is highly cost-effective compared to imported versions of Cobalt-60 teletherapy units. The Committee accordingly recommends the Government to encourage such indigenous manufacturing and promote collaborations between apex research bodies and Ministries/Departments in the country.**

**(Para 4.6.3)**

#### **Case Study: Average travel time to access Radiotherapy Facilities**

**The Committee notes that improving the prevention and screening scenario in cancer care would only bear results if the diagnostic infrastructure is ramped up to ensure there is matching of demand and supply. The Committee recommends the Ministry to improve both technological and human resources in the healthcare institutions as trained manpower and technology resources are complementary to each**

other. Improving the diagnostic infrastructure in the medical colleges and hospitals would improve the access and thus patients would not have to travel long distances to access treatment facilities.

(Para 4.7.5)

### **Imported Cancer Drugs**

The Committee recommends the Government to provide basic infrastructure to the manufacturers of drugs for manufacturing cancer drugs that are presently being imported at high price, in the country itself under Make-in-India Programme so that the prices can be reduced and made affordable. The Committee also recommends the Government to make an effort to support or incentivize the industry to go for R&D and start manufacturing high-end drugs in our country so that the country can become *atmanirbhar* or self-reliant. The Committee takes into account that the Department of Pharmaceuticals is supporting the pharmaceutical industry under the PLI Scheme. Under the said scheme the Department of Pharmaceutical gives an incentive of 5% to 10% for various kinds of new drugs to incentivize generic manufacturers to move towards new types of drugs. The Committee, accordingly recommends the Government to encourage the Pharmaceutical industry to manufacture costly cancer drugs, which are being imported right now, at the cheaper price on the line of Bhabha Atomic Research Centre (BARC).

(Para 4.8.3)

### **Pradhan Mantri Jan Arogya Yojana (PMJAY)**

The Committee observes that despite the launch of AB-PMJAY to increase universal health coverage, healthcare in India is largely financed through out-of-pocket payments and remains unaffordable for a large part of the population. Though initiatives like Ayushman Bharat and National Digital health Blueprint have created a foundation for health integration, the delivery of cancer care in the country remains largely fragmented leading to patient leakages within the health system and resulting in poor treatment outcomes. The Committee, however, hopes that AB-PMJAY and National Digital health Blueprint would go a long way in delivery of cancer care system.

(Para 4.9.3)

The Committee has been apprised that one among the five cancer insurance claims is by patient belonging to 36 to 45 years of age, thereby resulting into the loss or disruption of household income. As per the National Sample Survey Healthcare even average out of pocket spending on cancer care is too high. The out of pocket spending for cancer care in private facilities is about three times that of public facilities. About 40% of cancer hospitalization cases are financed mainly through borrowings, sale of assets and contributions from friends and relatives. Considering such a glaring gap in affordability when it comes to quality cancer care, the Committee feels that there is a strong need to make cancer care affordable through suitable interventions from both Government and private sectors.

(Para 4.9.4)

The Committee is of the view that adequate measures can be taken for convergence between state and central health schemes with similar beneficiary bases. The Committee observes that some State Governments have successfully implemented their own state-specific health insurance scheme on top of AB-PMJAY considering their local socio demographics and disease burden. In the opinion of the Committee state specific insurance has been highly beneficial to the community at large. The Committee understands that having both the depth and coverage the AB-PMJAY can increase more beneficiaries and better treatments. On similar lines, the governments should take steps towards the convergence of health schemes thus providing more comprehensive coverage in case of catastrophic expenses brought upon by cancer incidence in a household.

(Para 4.9.5)

The Committee finds that besides the devastating effect of cancer in terms of morbidity, the cost involved in managing the disease puts unbearable economic burdens on individuals, their families and on the nation. The high cost of cancer healthcare often leads to a substantial financial burden on the patient and their family. One third of household with individuals with cancer are estimated to spend more than half of their per-capita annual household expenditure on hospitalizations.

(Para 4.9.6)

The Committee takes into account all the measures undertaken by the Government for making cancer much more affordable without compromising on the quality of treatment given. Most curative treatment is affordable especially when patients get treatment under the AB-PMJAY scheme of the government. The upgradation of Government Hospitals with oncology departments and 25% reservation on cancer services provided in private hospitals for patients treated on government schemes will offer affordable cancer care to patients. Increasing funding for cancer research that evaluates low-cost technology, repurposed drugs and indigenization of equipment will reduce costs in the long run. The Committee understands that linking adherence to the NCG resource stratified guidelines to reimbursement under Government schemes will bring down costs. The NCG has also conducted group negotiations for cancer drugs which has resulted in procuring high quality drugs at 20 to 90% discount from MRP, which should be passed on to patients.

(Para 4.9.7)

The Committee takes into consideration that since the cost of newer therapies are expensive, therefore, the Government should leave no stone unturned in making the cancer treatment affordable. In this regard, the Committee recommends that a concerted effort must be continuously made to bring clinician scientists, industry & academicians, biotechnologists, cell biologists, bioinformatics, immunologists to develop Chimeric Antigen Receptor (CART-cell) therapy in the country. The Committee endorses the views of the Department of Biotechnology for the implementation of two projects, namely:

- (i) Development of genetically engineered „off-the-shelf“ and inducible CAR T-cell for cancer therapeutics;
- (ii) Research on glioblastoma stem cell-targeted T-cell immunotherapy using non-genetically engineered mesenchymal stromal cells.

(Para 4.9.8)

The Committee finds that the charge for cancer treatment is high in the Private Hospitals, therefore, more Government Hospitals should be established across the country for providing affordable cancer treatment. The Committee endorses the views of the Department of Atomic Energy that existing Government hospitals should be upgraded to create oncology departments; these departments should also have “private patients” who pay for their care, and partially subsidize the “free” patients who are not charged. Similarly, 25% reservation on cancer services provided in private hospitals should be earmarked for patients treated on government schemes. The measures so undertaken would ensure not only affordability of care but also ensure that the doctors in both Government and private hospitals deliver healthcare services and treatment of patients from all strata of society.

(Para 4.9.12)

The Committee takes into account that about forty percent of cancer hospitalization cases are financed by informal financial tools. A major part of treatment expenditure is availed from informal credit at high rates of interest. Due to high mortality rate in Cancer, the net outcome for the household happens to be an insurmountable debt when the earning member of the family demises. The Committee, therefore, considers that easily accessible credit line through formal channels is highly needed to fill the gap, however, at present there are few such medical/healthcare loans options available in the Indian market primarily offered by Non-Banking Financial Companies (NBFCs) charging interest rate as high as 13% to 15% and with limited loan amount. That again raises a concern of affordability, hence, it is imperative to encourage major nationalized banks to create such product which is affordable for the public to use it as an emergency fund. The Committee, therefore, recommends the Government to encourage Nationalised and Corporate Banks for creation of more credit tools to meet catastrophic healthcare needs in critical cancer care segments.

(Para 4.9.13)

### Standard Treatment Guidelines

The Committee is of the view a dual approach is required for planning a systematic National Cancer Plan. On the one hand the Government should make attempt to strengthen the existing centres to provide uniform standards of cancer care across the country and on the other hand, additional Government run cancer centres should be established to fill up the gaps in access to care breaking geographic barriers. The Committee, in this regard, recommends the National Cancer Grid, a large network of cancer centres, research institutions, patient groups and professional societies, to continue to yoke the responsibility of carrying out the first approach.

(Para 4.11.3)

The Committee appreciates the role and responsibility of the National Cancer Grid, an initiative of the Department of Atomic Energy, in taking care of about 60% of all of India's cancer burden and the Committee hopes that NCG, incorporating all the experience and vision of all stakeholders of cancer care in India will play pivotal role, unified and powerful voice in the fight against cancer.

(Para 4.11.4)

### Scientific Advancement

**The Committee understands that the scientific advancement and technological development has a direct co-relation with affordability of cancer treatment because affordable cancer treatment requires a multi-modality sort of arrangement involving modern technology like radiation therapy & linear accelerator, radio therapy technique, machines, manpower, surgical oncology, nuclear medicine, medical oncology, preventive oncology and palliative care. The Committee has been given to understand that the Sanjay Singh University has worked on micro-RNA as biomarkers for early detection of cancer, therefore, such initiative can be undertaken in the Country for the development of biomarkers with clinical trials and development of new tools for cancer screening and early detection of cancer.**

**(Para 4.12.6)**

**The Committee recommends the Government to procure and install the latest tools, techniques and equipments such as LINAC machine or PET scan in Government hospitals for cancer treatment at affordable cost because cancer treatment is not possible without PET scan machine as the same is one of the basic investigation needed for cancer treatment especially to diagnose the metastatic cases.**

**(Para 4.12.7)**

**The Committee takes into consideration that the various departments in SCTIMST provide comprehensive surgical and interventional treatment as part of oncology related services. The Committee believes that the Patients especially from the economically weaker section of the society from all states of country would avail the benefits of the services of SCTIMST for neuro-oncology related ailments.**

**(Para 4.12.8)**

#### **Patient Assistance Program (PAP)**

**The Committee further recommends the Government to encourage effective Patient Assistance Program (PAP) to enhance affordability of cancer treatment. Patient Assistance Programs (PAPs) make newer innovative therapies and treatments affordable for patients in India. The Committee feels that since the majority of patients end up paying for their treatments from their pocket, therefore, such PAPs could be of immense financial assistance. The Committee has been given to understand that the NPPA implements TMR for free supply of oncology drugs under Patient Assistance Program (PAP) and government supply at a pre-determined lower price. PAP is usually designed and sponsored by pharmaceutical companies to offer free units of the medicine against a unit purchased for the class of patients who are non-reimbursed or do not have sufficient insurance coverage which results in improved patient access and compliance with treatments. The Committee, therefore, recommends the Government to explore rational modalities for effective Trade Margin Rationalization (TMR) mechanism that can facilitate PAP programs for cancer patients.**

**(Para 4.13)**

#### **Tariffs and Taxes on Cancer medicines**

The Committee observes high Tariffs and Taxes on Cancer medicines as a matter of concern. As compared to other Asian countries in similar stages of development, import duties in India are very high although the basic import duties for pharmaceutical products average about 10 percent but as a result of the integrated GST (5 – 12%) imposed on imports, the effective import duty often *exceed 20 percent*. Furthermore, excessive duties on the reagents and equipment imported for use in research, development and manufacturing of biotech products make the cost of manufacturing cancer drugs too high. While certain essential and life-saving medicines may be granted exemptions from some of the taxes, the eligibility criteria are vague and subject to constant revision. The Committee, therefore, recommends that drugs and vaccines used in the prevention and treatment of cancer should carry minimum GST and should be exempted from customs duties. Such measures will bring down prices significantly and the benefit would be passed onto the patients directly.

(Para 4.14)

#### **Public Procurement Order (PPO)**

The Committee has been apprised that under the Public Procurement Order (PPO) of the government non-local suppliers are not eligible to bid in government procurement, except for some high value orders. Due to manufacturing complexities around patented, specialty the proprietary drugs are manufactured in select locations only and indigenization of these medicines in a short time span is impractical and will severely impact availability of these critical drugs. The Committee has been given to understand such ineligibility on the part of non-local suppliers is creating a major access barrier for a lot of patented, specialty and proprietary drugs to be reaching out to the patients in need. The Committee, therefore, recommends the Government to consider for allowing a PPO exemption for non-local suppliers in case of patented, specialty and proprietary drugs not produced in India.

(Para 4.15)

#### **Indian Council of Cancer Research**

The Committee is in agreement with the suggestion of Regional Institute of Medical Sciences (RIMS), Imphal Manipur for establishment of Indian Council of Cancer Research/State Cancer Epidemiology Centres to undertake & promote Cancer Research in India, contextual and relevant to the needs of the Country. The Committee is of the view that the proposed Indian Council of Cancer Research would create suitable research environment and provide appropriate infrastructural support. Besides that, the said council would also formulate framework for periodic training in research methods and good clinical practices for investigators.

(Para 4.16)

#### **Enhancing Affordability of cancer treatment**

The Committee recommends the Government to undertake the following strategic course of action for enhancing affordability of cancer treatment:-

- i. Strengthening District hospital with Oncology Wing (Surgery, chemotherapy & palliative care)**
- ii. Upgradation of the existing RCC to Cancer hospital**
- iii. Spreading awareness on utilization of central financial assistance to public & doctors for cancer treatment**
- iv. Opening of cancer patient accommodation and transportation centres in every district under Govt.support or NGOs.**
- v. Increased awareness among public and health workers about certified generic anti cancer drugs**
- vi. Increased availability of certified generic anti cancer drugs in the market.**

**(Para 4.17)**

#### **Prime Minister's views on cancer care management**

**Inaugurating the Homi Bhabha Cancer Hospital and Research Centre in Mohali, on 24<sup>th</sup> August, 2022, the Prime Minister envisaged that a good healthcare system doesn't just mean building four walls, but to prioritize holistic health care in health policy formulation. In this regard, the Committee endorses the Prime Minister's views on provision of health facilities in the country by working together on following six fronts:-**

- (i) promotion of preventive health care**
- (ii) Opening small and modern hospitals in villages**
- (iii) Opening medical colleges and big medical research institutes in cities**
- (iv) Increasing the number of doctors paramedical staff across the country**
- (v) Providing cheap medicines and cheap equipments to patients**
- (vi) Reducing the difficulties faced by patients with the help of technology.**

**(Para 4.18)**

**The Committee is of the considered view that the Central Government as well as the State Governments should work in tandem to improve the health infrastructure for treatment of cancer and other diseases.**

**(Para 4.19)**

#### **Academic Training and Research Activities**

**The Committee notes the various initiatives of the Department of Biotechnology in the field of cancer research and appreciates the initiative of signing the MoU on 22nd May 2019 between the Department of Biotechnology, Department of Atomic Energy & National Cancer Grid (DBT DAE NCG MoU) for supporting joint activities in the area of cancer research. The Committee acknowledges that the DAE has been spearheading in prevention, diagnosis and treatment of cancer in the country for more than five decades and the NCG which has come into existence recently to look after all the aspects of cancer throughout the country, hence the Committee hopes that the MoU will go a**

long way in revolutionizing the research in cancer with a greater budgetary support from the Department of Biotechnology.

(Para 5.2.7)

#### **Tata Memorial Center (TMC)**

The Committee recommends higher funding allocation for organizations like ICMR, DBT and DST for clinical and translational research that has the potential to change the practice in India and the world and which results in Ayurvedic formulations. Higher funding can also lead to rigorous testing of other plant products for novel indications or to mitigate toxicity using the technical know-how and research innovations at ACTREC.

(Para 5.7.7)

#### **Collaboration with International Cancer Research Organizations:**

The Committee appreciates the efforts of the Department of Biotechnology, ICMR and Tata Memorial Centre in collaborating with international organizations for cancer research and hopes that India-UK “Affordable Approaches to Cancer Initiative” shall bear fruit in the direction of taking cancer diagnosis and treatment to the last person in India.

(Para 5.9.4)

#### **CaResNER multidisciplinary programme, implemented by ICMR-NCDIR**

The Committee feels that as research on India centric cancer centres are receiving a great impetus from the Government of India through the AYUSH Ministry, novel compounds from Ayush products and Ayurvedic formulations, other plant products can be rigorously tested collaboratively between Ayush institutes and other institutes having modern technical know-how and research innovations like ACTREC, IISc, IITs, NIPERs and such other institutes. This can be enhanced further by testing these products/ innovations on cancer patients attending both the AYUSH hospitals and modern allopathic hospitals in the setting of large trials which will be acceptable to people in other parts of the world.

(Para 5.10.9)

#### **Scope for public-private partnership in the field of academic training and research activities for treatment of cancer:**

The Committee observes that Public-Private Partnership in the field of cancer research activities should be taken up on the format of the National Cancer Institute, USA. The Committee hopes that it will encourage investigators to come forward and do research based on the cancer scenario in India and therefore will be more useful in the Indian clinical setting. This should not be confined to the research activities only, but provision should also be there for support for publication in journals as well as circulation of results of these research activities.

(Para 5.11.6)

The Committee is given to understand that some Institutes of Eminence in the private sector are conducting research activities in the field of cancer - but that is confined to the aspect of basic sciences only. The Committee opines that it needs to be translated to the clinics for the benefit of the patients. The government should encourage agreements between these institutes in the private sector and hospitals in the public sector treating cancer patients where footfall of cancer patients have been found to be massive so that trials can be carried out resulting in “real-world” data, useful for the cancer scenario in India.

(Para 5.11.7)

The Committee further recommends that the government should devise strategies for linkages of cancer research with various industries/companies for funding under Corporate Social Responsibility (CSR).

(Para 5.11.9)

**Need for creation of national and international platform for knowledge sharing and technology transfer pertaining to cancer care and treatment:**

The Committee is given to understand that at present, cancer centers like Tata Memorial Hospital and ACTREC, Mumbai, Dr. B Borooah Cancer Institute, Guwahati and other such centers have MoUs (at the organizational level) with national and international organizations for promotion of academic and research activities. However, the Committee notes that for an all-inclusive platform, the National Cancer Grid shall take a bigger role for creating such a platform for collaborative/exchange program activities.

(Para 5.12.2)

**Make in India Approach in Technology Innovation in Oncology:**

The Committee expresses its concern that the National Cancer Registry Program covers just 10% of the population of India as of 2020 data and feels that the data is very crucial in the research activities. The Committee, therefore, recommends that the Government should build a unified database through systematic collection, analysis and use of epidemiologic data which will further help to define sustainable frameworks for Cancer control in the community and help in bringing out the desired researches. The Committee feels that through Cancer registries, the systematic tracking of Cancer outcomes can contribute to incredible advances in understanding the epidemiology of Cancer. Even greater potential exists in tracking the costs and benefits of therapies, stage of diagnosis, follow-up data on outcome and long-term survival after the Cancer diagnosis in a real-world setting.

(Para 5.13.1)

The Committee expresses the imminent need to build interoperability between the population based and hospital-based Cancer registries by adopting digitization of healthcare, which will improve the quality of data collection through standardization and by removing the duplications.

(Para 5.13.2)

The Committee feels that clinical trials of investigational new cancer drugs remain disproportionately concentrated in High Income Countries and the under-representation of racial and ethnical population such as India reduces the generalizability.

(Para 5.13.3)

The Committee notes that the gaps in the research from Indian perspective include the scarcity of reliable data, a paucity of clinical trials and lack of an environment conducive to research in academic institutions (Public), including research infrastructure, trained human resources, funding and willingness to conduct the research. The Committee, therefore, recommends that efforts to strengthen research capacity in India should be expanded to individual, organizational and institutional levels as working on all three levels is more likely to yield long-term results. The Committee also feels that building cancer research network and collaboration can work efficiently on shared problems and common research priorities locally and globally.

(Para 5.13.4)

The Committee observes that several interventions are required for fostering an innovation-based ecosystem in the country.

(Para 5.13.5)

#### **National Policy to Catalyse Research & Development and Innovation in the Pharma Sector in India**

The Committee is given to understand that India is an attractive investment destination for R&D. Hence, there is a need for a National R&D Policy“s whose intent is to effectively improve the investment ecosystem for the research-based pharmaceutical industry, through seeking to coordinate policies that range across strengthening regulatory frameworks that facilitate innovation and research in product development; incentivizing investment in Innovation; and an enabling ecosystem for innovation and research. The objective must also include facilitating faster introduction of innovative therapies for patients in India as an objective of regulatory simplification. The Committee recommends that for establishing a meaningful R&D ecosystem in India, it is critical to have a robust IP environment which does not allow frustration of patents. An effective IPR regime is an essential pillar to promote innovation. Therefore, IP protection and enforcement must find place in the National R&D Policy.

(Para 5.14)

#### **Harmonisation of Regulatory Norms**

The Committee feels that the Indian pharma sector needs greater alignment with the rest of the world - particularly with the developed western countries that are the largest export markets for Indian companies, and the peer group of BRICS nations that are at a somewhat similar level of development and regulatory competency. India can acquire a higher degree of harmonisation by adapting their rules and regulations to guidelines developed by the International Conference on Harmonisation (ICH) which aims to find a way to reduce global drug development time and costs while enhancing patient safety and quicker access to new medicines.

(Para 5.15.1)

## **Adopting „Reliance Pathway“**

**The Committee feels that adopting „Reliance Pathway“ will ensure faster and expedited approval in India as well and which in turn will ensure the drug reaches the patients faster and at the same time by when it will reach the overseas patients as the review process will be ensured in parallel. Adopting Reliance pathway in India, which considers the review of key countries and clears the innovative drugs in a very short time, which many countries in South Asia and Latin America have already adopted**

**(Para 5.16.1)**

## **Human Resource Planning**

**The Committee is of the view that there is a need of increasing the number of postgraduate seats and Super Specialty Seats in Oncology. The Committee, accordingly, recommends the Ministry of Health and Family Welfare to increase the number of seats in various disciplines of oncology along with increase in seats in MD in radiotherapy, M.Sc. in radiological physics etc. The Committee also recommends the Ministry to explore the introduction of two years' post graduate fellowship programme in various disciplines in oncology that are duly accredited by National Medical Commission.**

**(Para 5.18.3)**

**The Committee further notes that there is lack of adequate manpower to make the cancer centres fully operational. In the absence of specialized healthcare force, many super specialities remain defunct even after the establishment of the physical infrastructure. The Committee accordingly recommends the Ministry of Health and Family Welfare to take effective measures to fill the sanctioned posts in these Cancer Care Units. To avoid such delays in making the centres fully operational, the Ministry must make manpower provision at the time of sanctioning a project. The Committee is of the view that the State Governments must also play an active role in ensuring that the manpower in State-run Cancer Institutes is adequate. The Committee also notes that very few institutions conduct technical courses that produce paramedics and technicians that can take care of increasing load of cancer patients. The Committee accordingly recommends the Ministry to increase such courses as the trained manpower is fundamental to providing value-added-services to the patients which will help improve their quality of life.**

**(Para 5.18.4)**

**The Committee also recommends the Ministry to explore 25% reservation for in-service candidates for degree courses with agreement to serve cancer Institute for minimum 5 years. The Committee also recommends the Ministry/National Medical Commission to revisit the Teacher, Student ratio to accommodate PG/Super speciality students. The Ministry must also increase the number of hospital beds in the existing hospital to meet the NMC requirement for increase of seats. The Government may also explore providing stipendiary supports to all centers conducting PG/Super specialty courses.**

**(Para 5.18.5)**

**The Committee appreciates the Shared Hospital Income (SHI) scheme of Tata Memorial Centre wherein approximately 12 to 15% of overall hospital income is shared**

amongst medical staff. The Committee recommends the Ministry to implement similar Scheme across other cancer centres to retain qualified staff.

(Para 5.18.6)

The Committee notes that cancer cases in India are diagnosed at a later stage which is a major cause of high mortality to incidence ratio and increase in cancer care expenditure. The Committee strongly believes that a strong network of cancer care centres across the country would facilitate early diagnosis of cancer cases and greatly reduce the burden of cancer cases in India. The Hub and Spoke Model is an efficient distribution model of providing comprehensive cancer care by creation of hubs and spokes in all the States of the country. The Committee notes that TMC has worked in close contact with the State Governments to create hubs and spokes in States. The Committee believes that such collaborations will enable in further strengthening the cancer care infrastructure along with knowledge, skill and resource sharing. The Committee appreciates the work done by TMC and DAE and strongly advocates the need for establishing government funded hub and spoke model of cancer care across States. The Committee further believes that ensuring adequate human resource in Cancer centers under the hub and spoke model is also crucial for complete operationalization of the Centers.

(Para 5.18.8)

The Committee is given to understand that, TMC being the pioneer institute in cancer treatment, research and training, at present trains 60% of the country's workforce in cancer diagnostics and treatment and most of the researches in the field of oncology have also come from the TMC. The Committee observes that the number of oncologists, super specialists and nursing staff being trained at present is not enough to cater to the present need. The Committee further feels that with the plan of the government to spread the Hub & Spoke model in the aegis of TMC & NCG, the country would require a multiple number of oncologists as well as cancer caregivers in the next five years. The Committee is of the considered view that there is an imminent need to increase the academic training capacity to cope with the present and future requirements of oncologists as well as the caregivers.

(Para 5.18.10)

**Chitranjan National Cancer Institute (CNCI), Kolkata**

The Committee endorses the views of the CNCI and recommends that to improve the research quality in the country, the Government must ensure creation of good research environment, sophisticated instruments, collaboration of researchers and clinicians and a state of the art library in all the institutions conducting research in cancer diagnostics and treatment.

(Para 5.19.1)

The Committee observes that cancer research in India should be contextual and relevant to the needs of the country. Reliance only on research done in high income countries should reduce as they differ in the types of cancers, the socio-cultural and economic context, and health systems. The Committee recommends that all the medical

**institutions across India should prioritize research in addition to patient care and education as is being done at TMC.**

**(Para 5.19.9)**

**The Committee notes the initiatives taken by the CNCI in the field of research for cancer treatment by taking several measures for promoting clinical research and recommends that such initiatives and measures should also be replicated in all the government institutions to boost the research and outcome in the country.**

**(Para 5.19.12)**

#### **Department of Atomic Energy**

**The Committee is given to understand that TMC research has resulted in practice- changing protocols that reduce cost and are said to be a policy for the country, however the Committee feels that the opening of TMC centres in various parts of India will stimulate the percolation of practice-changing results in various parts of the country. Moreover, the large cancer workforce being trained at TMC will help to disseminate the evidence-based cost- effective solutions that have been discovered at TMC. The Committee further recommends that the Government should focus on opening more research centres throughout the country and earmark 20% of the research budget on oncology.**

**(Para 5.20.7)**

#### **Bhabha Atomic Research Centre (BARC)**

**The Committee appreciates the efforts of the scientists at BARC in developing products for affordable cancer treatment and notes that the indigenously developed products by BARC is made available at lower cost *vis-à-vis* the imported cost. The Committee recommends that the government should encourage more such researches by providing more opportunities and funding to the scientists. Research should also be prioritized for early detection of cancer cases so that the spread of the disease can be nipped in the bud and lot of human and financial resources of the country is saved. The number of research is of paramount importance in the present context because the number of new cases and types of cancer is growing. If the scientists are able to develop diagnostics for multiple types of cancer at an affordable price the vast Country like India can be better placed for checking this growth trajectory.**

**(Para 5.21.1)**

#### **Jawaharlal Institute of Post Graduate Medical Education and Research, Puducherry**

**The Committee also recommends that International Collaboration on Research methods Development in Oncology (CreDO) workshop should play the major role of research in cancer diagnostics and treatment by bringing the mix of clinician-researchers, trialists and statisticians together. The Committee feels that NCG funded multicentric collaborative research is also expected to bring transformation in the protocol of cancer treatment.**

**(Para 5.24.1)**

## **Integrated Health & Wellbeing (IHW) Council on promoting research in cancer**

**The Committee recommends that India specific research must be funded and encouraged to ensure that treatment models and therapies that are developed are done so based on Indian variations and not western ones. The Committee feels that research on innovative therapies, more effective drugs with fewer adverse effects, repurposed drugs, pharmacological combinations, and more is necessary because modern treatments are exceedingly expensive; and India-centric research on such issues can help cut down costs of treatments. The Committee further recommends the Ministry to carry out more research and studies on prevention, early diagnosis and screening of the different types of cancer.**

**(Para 5.25.1)**

### **Siddha Diagnosis Plan**

#### **Treatment**

**The Committee notes that Ayush systems can play a significant role at all phases of Cancer care continuum particularly prevention and palliative care. Therefore, the Committee recommends the Ministry to prioritize prevention and palliative care and put in concerted efforts to make Ayush verticals like Ayurveda, Homeopathy and Yoga viable and effective options in these aspects of cancer control continuum.**

**(Para 6.2.5)**

**The Committee is of the view that not just Ayurveda but all Ayush systems have a role to play in each of these facets *i.e.* curative, supportive, prophylactic or preventive and palliative cancer care with Ayurveda leading the way. The Committee feels that each of these areas require focused attention especially the curative and supportive aspects for cancer care management by Ayush.**

**(Para 6.2.7)**

**The Committee feels that for Ayush systems to make a significant impact in the cancer care continuum, it is essential that all the anti cancer Ayush drugs, therapies and tools must be tested for their efficacy and safety. Even the drugless therapies of Yoga and Naturopathy need to be focused upon for their immense benefits for cancer patients. The Committee believes that the need of the hour is evidence-based Ayush practices and treatments which can complement modern medicine further. It is, therefore, imperative to evaluate traditional practices scientifically and integrating the beneficial practices with the modern medicine.**

**(Para 6.2.8)**

## **HOMOEOPATHY**

**The Committee is of the view that the institutional arrangement for treatment as well as management of cancer under Ayush Systems is scattered and is not properly institutionalized. The Committee feels that the Ministry must play a proactive role in ensuring that a policy is framed for delivering cancer care facilities entailing preventive,**

curative treatments, supportive therapies, palliative care through Ayush institutions. Since Ayurveda possesses potential to lead in cancer care, it can take initiative and frame proper protocols and guidelines for cancer management so that standardized Ayush facilities and care is given to cancer patients for better outcomes.

(Para 6.3.10)

The Committee is given to understand that North-Eastern regions has higher incidence of cancer, thus the Committee expects that a Cancer unit gets operationalised soon in North Eastern Institute of Ayurveda & Homeopathy (NEIAH), Shillong. The Committee believes that Ayush Health and Wellness centres need to be strengthened and upgraded for delivering health facilities to cancer patients. Further, the Committee recommends that Ministry should work towards integrating non-pharmacological therapies of Naturopathy and Yoga with mainstream medical care as this may greatly help in reducing various adverse effects of conventional treatment and go a long way in strengthening cancer care through Ayush.

(Para 6.3.11)

The Committee highlights that with the growing popularity of Ayush systems and the immense faith of the people in these systems, various Ayush institutions must have their own OPD/IPD facilities for catering to cancer patients. At the same time, integrated cancer care set up of Ayush systems must be expanded on the lines of All India Institute of Ayurveda, Sarita Vihar, New Delhi wherein, homoeopathic physician, Ayurvedic physician and Unani physician provide integrated care to cancer patients visiting the institute. Similarly, like in NCI-Jhajjar, Centre of Ayurveda and Integrative Medicine unit should be established in all the 22 AIIMS across the country. The Committee, accordingly, recommends the Ministry to expand the scope of Ayush health facilities in the country and chalk out a plan of action in this regard.

(Para 6.3.12)

The Committee has been given to understand that Ayurvedic medicines have been found to possess potential to halt the progression of cancer. Ayush systems further have the capability of reducing considerably the adverse side effects of conventional cancer treatment through modern medicine. Certain Ayush anti-cancer medicines have been found to be useful in controlling the harmful effects of chemotherapy and radiotherapy and have been successful in helping cancer patients lead a better life. The Committee, accordingly, recommends to the Ministry to further conduct clinical trials for scientifically validating the claims made by Ayush systems in these areas of cancer management and document the positive outcomes. Such efforts will enhance the credibility of these systems. Apart from being crucial in improving the quality of life of cancer patients, it must be ensured by Ministry of Ayush that these medicines are cost effective too.

(Para 6.3.13)

#### **Budgetary allocation in AYUSH exclusively for cancer care and research**

The Committee finds that there is no separate budget for cancer care and research in various Ayush institutes. The Committee is of the view that given the pivotal role played by Ayush systems in management of cancer, focused attention through adequate fund allocation is required for expansion of Ayush cancer care facilities. The Committee, accordingly, recommends that to give impetus to cancer care facilities and

research, there should be separate fund allocation for the same. The Committee desires that the Ministry of Ayush should prepare an estimate considering the realistic requirement of its research fund for each research initiative and approach the Ministry of Finance for allocation of adequate research fund.

(Para 6.4.3)

The Committee strongly believes that Ayush systems of medicine can play a major role in Cancer prevention. The Committee acknowledges various measures like promoting awareness and sensitization about the diet, lifestyle and self-care. The Committee recommends the Ministry to give further impetus to awareness generation on diet and food ideal for consumption and food for avoidance. The Ministry should partner with NGOs and Civil Society Organizations to sensitize school and college students through events like debates and skit. Moreover, information handouts advising people to follow the healthy life style, diet and yoga based on the daily regimen, seasonal regimen and behavioral therapy should be distributed at Public Health Centres (PHCs), Community Health Centres (CHCs).

(Para 6.5.16)

The Committee also recommends the Ministry to organize more integrative screening camps, particularly in rural and remote tribal regions where people should be screened for cancer utilizing Ayush knowledge base. The Ministry should also extensively promote its Ayurveda Cancer prevention programme (ACPP) under which people, at high risk of cancer, having strong family history of cancer, those with habits of alcohol, tobacco, and other carcinogens are specifically targeted and are screened, sensitized and made aware about importance of screening and other lifestyle habits to prevent cancer.

(Para 6.5.17)

Emphasizing on the potential of Ayush systems to play a major role in prevention of various types of cancers, the Committee recommends the Ministry to explore starting a "Swastha Aahar (Healthy Food)" pakhwada on the lines of Hindi and Swachhata Pakhwada atleast twice a year preferably around International Yoga Day and Gandhi Jayanti. During the mission, people should be encouraged to abstain from consuming packaged food, unhealthy food, extensive outreach and awareness programmes can be planned, essay and quiz competitions around the "Fight Against Cancer" theme can be organized in schools, colleges and housing societies. The Ministry should also find out ways to use social media for disseminating such valuable information to the length and breadth of the country.

(Para 6.5.18)

**Clinical registry for reporting of cancer cases and its outcome subsequent to treatment by the AYUSH practitioners /hospitals**

The Committee believes that cancer registries are very important as they collect accurate and complete cancer data that can be used for cancer control and epidemiological research, public health program planning, and patient care improvement, and finally all of these activities reduce the burden of cancer. The Committee is in agreement that comprehensive clinical documentation of cancer patients using Ayurveda, Homeopathy and Siddha treatment as a standalone or add-on therapy should be done. Ayush specific cancer registries can help in understanding the

efficacy of these treatment methods which would grant these alternative forms of treatments much needed legitimacy. Therefore, the Committee, recommends the Ministry to put concerted efforts to operationalize the Portal/ Cancer Registry in Ayurveda and other Ayush systems and ensure that these registries have inter-linkages with other existing registries like Cancer Registry of ICMR.

(Para 6.6.3)

The Committee would also like to be apprised of the experiences/feedback shared on the Network for Ayush Cancer Care (NFACC) under AIIA regarding clinical experiences of treating different cancerous conditions and whether the information so shared has been put to good use in evaluating the data for formulating cancer treatment protocol and guidelines. The Committee further recommends the Ministry to engage State Governments for initiating State Cancer Registry in their own States.

(Para 6.6.4)

#### **Improving Quality of life of cancer patients through AYUSH systems**

The Committee is of the firm view that Ayush systems can have significant impact in improving the quality of life of cancer patients through its various therapies and palliative care services. It is felt that a multi-disciplinary approach may go a long way in cancer care continuum which is cost effective and help in alleviating the various side effects of cancer treatment.

(Para 6.7.5)

The Committee feels that drug development program is an important area which needs to be focused upon. All out efforts must be made to study the herbal, mineral & herbo-mineral drug for its anticancer effect & efficacy in various combination. The Committee would like the Ministry to ensure that all such cancer screening, detection and other care by Ayush systems are properly documented.

(Para 6.7.6)

#### **Integrative Oncology: Integration of allopathic as well as AYUSH systems for cancer care and management**

The Committee commends the Ministry of Ayush for its initiatives on integration of allopathic as well as Ayush systems for cancer care and management. The Committee recommends the Ministry to develop a detailed format for uniform and comprehensive documentation of cancer patients using Ayurveda treatment as a standalone or add-on therapy, the Committee is of the opinion that the database generated may be used for exploring ways to further improve the integration of allopathic as well as Ayush systems. The Committee recommends the Ministry to put concerted efforts in setting up integrative oncology centres in addition to collocation of Ayush multi systems under one roof.

(Para 6.8.2)

The Committee is of the view that collaboration with reputed cancer institutes like TMC, AIIMS, New Delhi, and DRDO in cancer research and treatment is a step in the right direction. The Committee believes that such collaborations must be expanded and integrative cancer care services must be made available for cancer patients

throughout the country. A National Centre of Excellence in the field of Integrative health care and research in Oncology by upgrading CARI is a wonderful initiative by the Ministry of Ayush which necessitates proper monitoring of the project so that this National Centre of Excellence is started as early as possible.

(Para 6.9.12)

Attention of the Committee has been drawn to the drug-drug interaction issues with chemotherapeutic agents. The Committee believes that this is an area of concern and require further investigation and research. The Committee, accordingly, recommends the Ministry to prioritize this area of concern and focus on studies on this issue for clearing the doubts and inhibitions of oncologists regarding the drug-drug interaction and efficacy of treatment.

(Para 6.9.13)

The Committee notes that several allopathic institutions are integrating Yoga interventions in cancer patients. Considering the efficacy of yoga in management of fatigue, chemotherapy induced nausea and emesis, improvement in quality of life and reduction in anxiety, depression and distress in cancer patients undergoing conventional treatment, the Committee recommends the Ministry to work towards getting yoga included in oncology guidelines for treatment of Cancer.

(Para 6.9.14)

The Committee takes note of the project entitled “Integration of Unani Medicine with National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS)” which was initiated at Lakhimpur Kheri, UP. The Committee would like to be apprised about the performance and current status of life style clinics that were established under this project at District Hospital CHCs. Considering that the project was successful in propagating Unani System of Medicine, the Committee recommends that the project must be continued further and similar projects should be started in other districts of the country.

(Para 6.9.15)

**NAM**

The Committee has been given to understand that the AYUSH HWCs being operationalized under the National Ayush Mission will be converged with the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) so that primary screening at the grass root level will be co-ordinated through AYUSH HWCs as per availability. The referral services will be catered by the AYUSH units at District and Community Health Centre (CHC) NCD cells. The Committee appreciates this step of both the Ministry of Health & Family Welfare and Ministry of Ayush and is of the view that this facility of primary screening at Ayush HWCs and referral services by Ayush units at district and CHC level must be expanded in all the States. The Committee also recommends the Ministry to engage and sensitize State Governments to avail financial assistance under NAM for cancer screening at HWCs and referral services and send their State Annual Action Plans accordingly.

(Para 6.9.19)

The Committee feels that the Indian systems of medicine should be used appropriately in management of cancer. The various limitations in access to quality and affordable cancer care can be addressed through utilizing both the modern as well as Ayush systems. The need of the hour is to integrate both modern and Ayush systems of medicine so that cancer care is better managed in the interest of the cancer patients. Therefore, the Committee recommends the Ministry to work towards integrating Ayush with the modern system of medicine to harness its potential benefits. The Committee believes that the patients should have the option for going for conventional treatment or a combination of both modern medicine as well as Ayush systems for better outcomes. Extensive basic and clinical research in cancer should be conducted by Ayush institutions in collaboration with institutes like AIIMS and Tata Memorial Centre to generate evidence of the benefits of Ayush interventions through rigorous clinical documentation and well-conducted studies so as to develop the integrated approach for cancer treatment. The Committee recommends that Ayush knowledge and manpower should be utilized in prevention and screening camps organized under National Cancer Control Programme.

(Para 6.9.20)

**Evaluation of AYUSH Products at Advanced Centre for Treatment, Research & Education in Cancer (ACTREC), TMC**

(Para 6.10.2)

The Committee appreciates the integrated cancer care being provided by TMH in providing leadership for advancing integrative Ayush approaches through its various efforts by creating evidence for integration of Ayush into standard protocols of cancer care, assisting Ayush Ministry in evaluation and monitoring of related guidelines, policies and legislation, cultivation and conservation of medicinal plants and its potential benefits in cancer care etc. An indigenous medicinal plant research facility for cultivation and conservation of such plants along with skill development of tribal population for research is a novel initiative for recognizing the immense potential of medicinal plants for cancer treatment.

(Para 6.10.3)

The Committee also appreciates the evaluation of Ayush drugs by Advanced Centre for Treatment, Research & Education in Cancer (ACTREC), TMC. Such evaluation and scientific studies will bring out credible results which will go a long way in furthering the integrative oncology. This will also ensure efficacy and safety of Ayush drugs like carcitol for its anti-cancer properties. The Committee recommends to the Ministry to promote such evaluation studies of all Ayush drugs so as to provide scientific backing to efficacy of Ayush drugs.

(Para 6.10.4)

The Committee takes into account that modern anticancer approaches such as surgery, chemotherapy, radiation, hormonal treatment, targeted therapy, and immunotherapy have increased survival for many types of cancer, on the contrary traditional methods often relies on ancient theory and wisdom as well as thousands of years of empirical practice with people of a particular culture and community. The treatment focuses on the person with the illness rather than the disease itself and embraces the holistic nature of health as the interplay among body, mind, and spirit.

**The Committee, therefore, strongly recommends that Ministry of Ayush and Ministry of Health and Family Welfare to chalk out Action Plan to promote integrative Oncology having the best elements of both the systems of medicine.**

**(Para 6.10.6)**

**The Committee finds the philosophy and treatment of both the modern/conventional and the traditional system of medicine quite interesting and is of view that given the popularity of Ayush systems in the country , it would be much better to integrate and collaborate both the systems for the benefit of the cancer patients. Whatever the reasons maybe for the patients opting for one of two systems or both the systems together, it is high time to put in place a policy for integration of both the systems in management of cancer. The Committee believes that Ministry of Health and Family Welfare and Ministry of Ayush must work towards an integrative oncology policy and lay down guidelines for such treatment protocols and required health infrastructure for the same. Example of TMH evolving an integrative cancer care approach by including Ayush must be replicated by other premier cancer institutes for the benefit of cancer patients.**

**(Para 6.10.7)**

### **Cancer Research in AYUSH**

**The Committee observes that there is huge potential in Ayurveda for management of cancer at various levels particularly in prevention and rehabilitation. The Committee, therefore, recommends that effect and impact of Ayurveda as a whole system should be explored in the various conditions and stages of cancer. The Committee notes that Ayurveda management versus Methotrexate in Rheumatoid Arthritis (AMRA) study has shown that whole system approach of holistic science can be explored in clinical research setting. The Committee further recommends that Ministry should embark upon to replicate AMRA study and its findings in cancer care and management.**

**(Para 6.11.11)**

**The Committee acknowledges the research work being carried out by ITRA, Jamnagar. The Committee would like to be apprised about the findings of these two clinical research studies. The Committee recommends the Ministry to identify more areas for research and allocate more funds for clinical studies. The Committee also recommends the Ministry to identify ways for incorporation of the findings of clinical research studies in the prevention, treatment and palliative care methods.**

**(Para 6.11.12)**

**The Committee takes note that the Central Council for Research in Siddha has identified a key concern area in management of cancer i.e. side effects of cancer therapy faced by cancer patients during their illness. The Committee recommends that the institute expedite research studies under its "Pharmacovigilance" program that helps detection, prevention and management of drug-induced adverse reactions. The Committee also recommends the Ministry to fast track establishment of Siddha Integrative Palliative Care Therapy in CCRS, New Delhi, and Safdarjung Hospital, New Delhi.**

**(Para 6.11.16)**

The Committee takes into account the clinical research studies undertaken by CCRH for ascertaining the impact of homoeopathy in combating the side effects of chemotherapy in cancer patients and its efficacy in management of Cancer. The Committee recommends the Ministry to document and publish the outcomes of such clinical research studies and further encourage clinical research studies on Homeopathy so as to have enough scientific validation of the Homeopathic measures on management of Cancer. The Committee also intends to know the Ministry's vision for translation of the findings of the clinical research studies on Homeopathy into Clinical practice and how the integration within different Ayush verticals for management of cancer is being envisioned.

(Para 6.11.18)

## Ayurgyan

The Committee appreciates the Ministry of Ayush for identifying key concern areas in strengthening Cancer Care Plan and Management in Ayush. The Committee recommends the Ministry of Ayush for setting up a comprehensive framework to address these challenges on priority basis. The Committee recommends the Ministry to put concerted efforts in carrying out clinical trials adhering to the international guidelines/standards on clinical trials, such clinical trials would give the Ayush measures required legitimacy and scientific validation. The Ministry should also work towards creating a database of medicinal plants and natural compounds having potential for management of Cancer. Studies for testing the efficacy and safety of Ayush drugs along with modern medicine for management of cancer must be undertaken. The framework should also have provisions for addressing challenges posed by medico legal and ethical issues. Insurance coverage for integrative oncology care need to be made available for cancer patients. The Committee believes that even though integrative oncology is slowly evolving, efforts must be made by the Ministry to sort out areas of concern and address the visible challenges and help in creating an environment where Ayush can contribute in cancer management along with conventional treatment.

(Para 6.13.1)

The Committee recommends the Ministry to take note of all the suggestions made by Ayush institutes for better management of cancer care by Ayush. The Ministry must provide all out support to these institutes from resources to adequate funding for ensuring training of Ayush manpower in integrative oncology, development of suggested infrastructure for the same, cost effective diagnostic labs for patients, engagement of oncologists, evaluation of Ayush drugs and cancer research.

(Para 6.13.6)

The Committee would like to draw the attention of the Ministry of Health and Family Welfare and Ministry of Ayush towards Chinese traditional system of medicine which is properly integrated in conventional cancer treatment in China. The Committee, time and again, has been recommending integration of Ayush systems with modern medicine on similar lines as done in China and believes that such an integration would pave for holistic care of patients suffering from any disease which becomes all the more important in cancer care and management.

(Para 6.13.7)

## **Monitoring and Supervision**

**The Committee is given to understand that the Government of Kerala has integrated palliative care with healthcare policy at all levels in a three-tier system. Local governments and over 350 non-government and community-based organizations are now providing Palliative Care services, largely home-based. The Committee observes that the Kerala Model places a strong emphasis on community participation and volunteerism integrated with Primary Health Care system especially through dedicated nurses under the overall leadership of local governments.**

**(Para 7.4.6)**

**The Committee notes that Palliative care in India is still at a very nascent stage except the State of Kerala that boast of a comprehensive Palliative Care Services. The Committee takes into account that lack of a robust National Palliative Care Policy and institutional arrangement in palliative care across States has resulted in neglect of the Palliative care in India. The Committee understands that with increasing incidence of chronic lifestyle diseases and cancer, there is a need to change the approach to palliative care and bring in a comprehensive policy.**

**(Para 7.4.7)**

**The Committee is of the opinion that along with an institutional hospital based approach led by health professionals, the Ministry must also explore the possibility of adopting community based care at macro level in the country. The Committee, accordingly, recommends the Ministry to integrate palliative care with the healthcare policy at all levels and make active use of the community based resources. The Committee recommends the Ministry to increase community engagements and participation from civil society. The Committee may also explore the involvement of Private Sector in starting independent Palliative care institutions in different communities. There is a need to develop a mechanism wherein the trained professional can identify patients' needs and provide home care at all levels.**

**(Para 7.4.8)**

**The Committee further finds that pain relieving drugs form important part of the Palliative care. The Committee notes that the Indian Government has recently allowed private companies in the strictly regulated sector of processing opium which is used to make medicines for relieving cancer pain. The Committee reckons that there are risks associated with opium addiction and its illicit trade, however, the Committee believes that making such drugs available in Cancer Centers for pain control is crucial for providing better Palliative Care. The Committee, therefore, recommends the Ministry to ensure that effective measures are taken to ensure that cancer pain controlling medication is easily available at Palliative Care Units and Cancer Centres.**

**(Para 7.4.9)**

**National health systems are responsible for including palliative care in the continuum of care for people with chronic and life-threatening conditions and linking it to prevention, early detection and treatment programmes. Hence there is a need for developing health system policies that integrate palliative care services into the structure and financing of national health-care systems at all levels of care. Policies are required for strengthening and expanding human resources, including training of existing health professionals, as well as educating volunteers and care takers. A medicine policy which ensures the**

availability of essential medicines for managing symptoms, in particular opioid analgesics for the relief of pain and respiratory distress is required.

(Para 7.4.10)

The Committee is agreement with the views of the National Cancer Institute, Jhajjar on the Palliative Medicine front, which has been designated as the WHO centre for next five years. The Committee recommends that the policy of the Government should be that each medical college should have a Palliative Medicine Department and the availability of Morphine and technical expertise to prescribe Morphine must also be present throughout the country.

(Para 7.4.11)

#### **Palliative Cancer Care by AYUSH Systems**

The Committee acknowledges that the Ministry has come up with Ayush Palliative services- KARUNYA and has included it in the National Ayush Mission. The Committee is of the opinion that palliative care in Cancer is very important as it plays a vital role in providing relief from pain and other distressing symptoms, it also aims to integrates the psychological and spiritual aspect of patient care.

(Para 7.5.7)

The Committee believes that Ayurveda interventions should be used for the palliative cancer care. The Committee recommends that palliative care facilities at Ayush hospitals should be upgraded through the strengthening of the manpower in terms of training in intra-Ayush integrative oncology. The Ministry should further improve its presence in the rural and remote areas and further train and empower Ayush faculty as trained manpower in intra-Ayush integrative oncology and the upgraded facility will definitely deliver good palliative cancer care to the needy in the remote and rural area in more economical way. The Committee also recommends that facilities for palliative care for cancer patients on the lines of Integrative Cancer Care Unit of AIIA, should be established in other institutes under the Ministry of Ayush.

(Para 7.5.8)

The Ministry may also apprise the Committee about findings of the research studies on Yoga & Naturopathy and how they have fared in reduction of side effects of cancer treatment and improving of psychological stress levels. The Committee further recommends that all non-pharmacological palliative therapies of Naturopathy and Yoga should also be started in all the Health and Wellness Centres of Ayush. The Ministry may also apprise the Committee about the details like number of patients benefited, number of care givers and Unani professionals working in the 18 Unani clinical institutes providing palliative care in Unani medicine.

(Para 7.5.9)

The Committee notes that the Ministry of Ayush through its research council runs "Swasthya Rakshan Programme" to provide health care facilities at the remote/rural areas and the same can be utilized for providing similar facilities like screening, follow up and prevention strategies through mobile units to cover rural and remote regions of the country. The Committee appreciates this imitative of the Ministry and recommends it to further expand the outreach of such mobile units to rural and remote areas for cancer prevention and screening.

(Para 7.5.10)

## **Medical Cannabis as Alternative Medicines**

**The Committee has been given to understand that western countries are now waking up to the benefits of medicinal cannabis as the first line agent for management of pain, nausea and other specific symptoms including chronic pain, epilepsy, chemotherapy induced nausea and vomiting, symptoms associated with terminal illness, sleeplessness, anxiety, depression etc.**

**(Para 7.5.11)**

**The Committee has been informed that there are presently two cannabis products - cannabidiol (CBD) and tetrahydrocannabinol (THC). Both these products have huge potential for palliative care of cancer patients by giving pain relief as well as a sense of peace in terminally ill-patients without the side-effects associated with other medicines. Both these products have the potential to improve the quality of life of cancer patients. Hence, a concerted effort by all concerned stakeholders starting from Government to the Legislature, Pharma companies, Research Institutes to Medical professionals need to consider using such alternative medicines to give terminally ill cancer patients to live a life with dignity.**

**(Para 7.5.12)**

## **Ministry of Chemicals and Fertilizers**

**The Committee desires that DHR should undertake a project to study and find out reasons for increase of Cancer cases in the country, region-wise and Cancer-site wise in male and female. The study may also look for any direct correlation of consumption of higher agrochemicals i.e. Pesticides with increasing incidence of cancer.**

**(Para 8.2.2)**

## **Progressive Foundation**

**The Committee is in agreement with the suggestions of Progressive Foundation that the Government should create corpus/fund for supporting Cancer patients under any scheme. This scheme may invite donation from philanthropic sources as well as from Corporate Social Responsibility (CSR) contributions of the companies. The Committee feels that provision for Cancer cess/ transport toll for cancer should also be considered.**

**(Para 8.4.2)**

## **Amrita Institute of Medical Sciences**

**The Committee concurs with the suggestions of the Amrita Institute that the Government must focus on methods of early detection with a clearly defined pathway for further management once diagnosed. The Government may encourage medical colleges to adopt a village, block, town or district to promote ways and means for cancer prevention and encourage people to undergo screening. The Ministry should also work on establishing 'state of the art' equipment and expertise in academic and tertiary centres for Cancer treatment. The Government may also consider better compensation**

packages which are more rational, insisting on guideline based treatment and having a cap on pricing of certain therapies/treatments under the Ayushman Bharat scheme. Further such packages should also include treatment portability with the power to transfer the medical documents of the patients to their choice of hospital/treatment facility.

(Para 8.5.5)

**Rajiv Gandhi Cancer Hospital, Rohini, New Delhi**

The Committee recommends the Ministry to put concerted efforts for inclusion of Chapter on Cancer/ Non Communicable Diseases in Environmental Studies and Ecology in middle, secondary and senior secondary classes. The Chapter must include aspects like awareness about Cancer, preventive measures, different causes of Cancer, importance of screening and early detection etc. Children and youth of the country should be informed about healthy lifestyle and healthy diet.

(Para 8.7.1)

The Government should also consider establishing an Indian Institute of Clinical Excellence which can look at formulating Standard Treatment Protocol (STP) and guidelines and other ways for cost-effectiveness of treatment methods.

(Para 8.7.2)

**Jawaharlal Institute of Post Graduate Medical Education and Research (Jipmer), Dhanvantri Nagar, Puducherry**

The Committee agrees with the view of JIPMER that regulatory environment in the country requires a change to encourage new and indigenous drug development for Cancer which can reduce the cost of drugs. The Committee recommends that Government through relevant bodies like BIRAC, DBT, and DST should provide more support for development of real world evidence (RWE) as many cancers are rare and it will be difficult to have randomized trials for all cancers. The Committee notes that despite DPCO (Drug Price Control Order) by NPPA, the Ministry should put in more efforts to regulate the price of cancer drugs in the country.

(Para 8.8.1)

**Indian Cancer Society, Mumbai**

The Committee is dismayed with the fact that all the Government schemes both at the Central and the State level are primarily for BPL section. The detection of cancer to any family member brings the whole family to poverty. The Committee, accordingly, recommends that concerted effort should be made to have provisions for cancer treatment of patients from middle income group who are not covered under any Government or private insurance scheme.

(Para 8.10.1)

The Committee has been given to understand that under the revised CSR guidelines by the Government there is provision for mandatory contribution of 2% towards Corporate Social Responsibilities. In this regard, the Committee recommends

**the Ministry to co-ordinate with the relevant Ministry and release a directive to suitably prioritise the CSR funds for Cancer Care activities.**

**(Para 8.10.2)**

#### **APOLLO Hospitals**

**The Committee is in agreement with the view that integrated national labs dedicated to early diagnosis should be established preferably in all the districts of the country. Similarly, national reference labs for Radiology, and Pathology mandated for diagnosis of the screening patients must be formed.**

**(Para 8.16.1)**

#### **Fortis Healthcare Limited**

**The Committee recommends that the Government must seriously consider tax cuts on expensive equipment such as Linear Accelerators; PET-CT etc as this would considerably reduce fixed cost and encourage setting up of new cancer centres across India.**

**(Para 8.17.1)**

#### **Pfizer Products India Private Limited, Mumbai**

**The Committee is of the view that the Government should consider exempting certain drugs originating from countries having well-regulated clinical trial processes from local clinical trials; this would help in expediting oncology drug approvals. Similarly, approval processes for anti-cancer drugs should also be further strengthened by making them time-bound, predictable, and transparent in implementation.**

**(Para 8.18.4)**

#### **Kidwai Memorial Institute of Oncology**

**The Government is in agreement with the view that the Ministry must work towards formulating a National Childhood Cancer Comprehensive Management Policy which involves Early Diagnosis, Shared Care, Integrated Paediatric Oncology Palliative Care across the Public Health Facilities. The Committee recommends that the Ministry may revamp the Rashtriya Bal Swasthya Karyakram (RBSK) to include the provisions of Cancer Care, treatment and Management.**

**(Para 8.22.1)**

#### **Postgraduate Institute of Medical Education and Research, Chandigarh**

**The Committee recommends the Ministry to improve the Cancer screening, diagnostic and treatment infrastructure of the PHCs, CHCs and District Hospitals. Every district hospital should be equipped with the facility of infusion of standard**

chemotherapy protocol. Similarly, every medical college in the country must be provided facility for image guided biopsy facility along with immunohistochemistry testing. The Committee recommends the Ministry to encourage the tertiary facilities like AIIMS, PGIMERs, SGPGI and other medical institutes of national importance to mentor and train existing medical staff of district hospitals for screening, diagnosing, administering standard chemotherapy and to manage patients with basic side-effects of anticancer treatment.

(Para 8.23.1)

The Committee appreciates the efforts of Stakeholders in enlightening the Committee Members on various aspects of Cancer care, treatment and Management. The suggestions of stakeholders have been well taken by the Committee while considering various issues concerning the Cancer care and management and based upon these suggestions, the Committee firmed up its observations and recommendations. Still, there is a possibility that certain valuable suggestions of the Stakeholders might have missed the attention of the Committee. Therefore, the Committee urges upon the Government to pay heed to those suggestions of the Stakeholders too, while formulating Policy and Guidelines on Cancer care, affordability, treatment, research and palliative care for Cancer patients.

(Para 8.23.2)

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