imPACT Review

### Cancer Control Capacity and Needs Assessment Report

### submitted to the Ministry of Health, Nutrition and Indigenous Medicine

Sri Lanka

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International Agency for Research on Cancer

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## Acronyms and Abbreviations

ASR	Age Standardized Rate
CME	Continuous Medical Education
CSO	Civil Society Organization
СТ	Computed Tomography
EPI	Expanded Programme of Immunization
EPHS	Essential Package of Health Services
FCTC	Framework Convention on Tobacco Control (WHO)
GAVI	Global Alliance for Vaccines
GICR	Global Initiative for Cancer Registry
GNI	Gross National Income
HBCR	Hospital-Based Cancer Registry
HBV	Hepatitis B Virus
HIV	Human Immunodeficiency Virus
HPV	Human Papillomavirus
IAEA	International Atomic Energy Agency
IARC	International Agency for Research on Cancer
LMI	Low and Middle Income (countries)
MRI	Magnetic Resonance Imaging
NCCP	National Cancer Control Plan
NCD	Non-Communicable Disease
NGO	Non-Governmental Organization
ORL	Otorhinolaryngology
PACT	IAEA Programme of Action for Cancer Therapy
PBCR	Population-Based Cancer Registry
PSA	Prostate-Specific Antigen
RT	Radiotherapy
STEPS	STEPwise approach to Surveillance (WHO)
US	Ultrasound
VIA	Visual Inspection with diluted Acetic Acid
WHO	World Health Organization
WHO-PEN	World Health Organization Package of Essential Non-Communicable
	Diseases
WWCs	Well Women Clinics
HLCs	Healthy Lifestyle Centres

#### **Executive Summary**

According to GLOBOCAN estimates (2018), each year 23 530 new cancer cases and 14 013 cancer related deaths are recorded in Sri Lanka. The most common cancers among women are breast, cervix, thyroid and ovary. In men, the most common cancers are oral cavity, lung, oesophagus and colorectal. In terms of number of new cases and most prevalent types of cancer, national data are very similar to GLOBOCAN estimates, though latest data are available from 2014. The Ministry of Health statistics from the same year, ranks cancer as the second leading cause of hospital deaths after ischaemic heart disease, with 24 mortality cases per 100,000.

National cancer surveillance system relies on two major population-based cancer registries: the Sri Lanka Cancer Registry (SLCR) and the Colombo District Cancer Registry (Colombo PBCR). Both generate minimum incidence rates, very limited mortality data, no survival rates data and therefore don't fulfil all the essential elements of a population-based cancer registry. Cancer is not a notifiable disease in the country, which would help with regular, accurate and timely reporting at national and regional levels. The opportunity to improve the system includes focusing on the wide list of institutions possessing relevant cancer data. In addition to hospitals, this includes health insurance agencies, cancer screening programmes and the vital statistics office. All these stakeholders should be considered while drafting the cancer registry legal framework to establish cancer as a notifiable disease.

Healthcare in Sri Lanka is delivered via a hybrid system, mainly composed of public and private sector. Allopathic medicine is predominant compared to indigenous traditional medicine. The public sector model offers free services at all levels of health care. 90% of inpatient care is delivered within the public sector. Outpatient care is delivered more equally between the public and the private health sector. Although cancer-specific data are not available, it is assumed that a similar distribution exists. An important challenge of the health system are the inequities in availability of cancer services across provinces. Geographical access is a constraint for patients living outside major health centres.

The health system response to cancer is translated into the main Government health policy, the National Cancer Control Plan (NCCP, 2015). The plan is well structured, and its scope and objectives are still relevant for the context. An important missing component is the action plan that should be developed in line with the recommendations of the imPACT Review. In addition, other existing health policies (e.g. Strategic Framework for Development of Health Services) constitute an opportunity for the NCCP, in terms of coordination, synergies and resource sharing. The established National Advisory Committee on cancer control is an important platform to guide the Ministry of Health. Most of the stakeholders are represented, except for the civil society sector. The Committee would benefit the establishment of technical subcommittees that can provide expertise and assist in the detailed cancer control planning.

Considering the specific cancer burden, tobacco control activities in Sri Lanka are priority. Based on the latest surveys (2015), tobacco use is much more prevalent in men than in women. Although the country has a comprehensive tobacco control programme, it requires strengthening in terms of smokeless tobacco control. In 2017, Sri Lanka implemented a ban to

both imported and locally produced smokeless tobacco products. Locally produced betel quid is officially banned since 2016. However, this product is widely available at a very low cost. National awareness campaigns against smokeless tobacco habit are challenging to implement because of the negative cultural impact it could have. Betel quid is a deep-rooted lifestyle habit, mostly chewed by the elderly and the rural communities (both men and women).

In terms of vaccine preventable cancers, Sri Lanka has included HBV in the Expanded Programme of Immunization (EPI) since 2003, with 3 doses at 2, 4, 6 months and high coverage (99%). There is no birth dose and no plan to introduce a birth-dose vaccine. Sri Lanka has a policy of immunizing healthcare workers at risk of HBV. HPV vaccination started in 2017, using 2 doses of HPV quadrivalent vaccine. This is a compulsory school-based programme targeting 10 to 11 years old girls. There is also a programme covering out-of-school girls through community-based clinics. The coverage is above 90%.

In terms of cancer early detection, the programme in Sri Lanka is focusing on oral, cervical, breast and thyroid cancers. Most of the patients are diagnosed at a late stage (III and IV): 33% for breast cancer, 52% for cervical cancer and 72% for oral cancer. Early detection is provided in several health facilities in the public sector. The Well Women Clinics programme at primary health care level, targets women aged 35 and 45 for breast, cervical and thyroid cancer screening. The Healthy Lifestyle Centres, also primary health facilities, provide prevention and early detection of the main non-communicable diseases (in men and women), as well as breast and oral cancer screening. A wide network of public dental clinics is dedicated to oral diseases.

The oral cancer screening is an opportunistic programme, well-documented with detailed guidelines. Oral cancer is the most common cancer in men. It is usually diagnosed in communities with low socio-economic status. The screening programme has a good network of health facilities and a good referral system from primary health care to specialized oral and maxillofacial facilities. However, most of the patients prefer using traditional medicine to avoid surgery, leading to late referral and advanced stage at diagnosis. Another challenge is that the high-risk population is difficult to reach and convince to stop their habits for cultural reasons.

Sri Lanka set the objective to reduce cervical cancer burden by 60%. Women can be screened at Well Women Clinics. Initially, screening was opportunistic and since 2007, it is an organised programme, with a defined target group woman aged 35 and 45 (included in 2018). The primary screening test is the conventional cytology Pap smear. Issuing cytology reports takes 1 to 2 months on average, but sometimes much longer. In 2018, a pilot project using HPV-DNA as a primary screening test was conducted. The results are under completion but there are concerns for scale up due to affordability and sustainability issues, i.e. cost of consumables. Linked to this demonstration project, in 2020, UNFPA will perform a cost-benefit analysis of HPV-DNA testing as a primary screening test. In 2018, the participation to screening among women aged 35 was 61.2% and 15% in women aged 45 (recent introduction). The performance is measured only through participation rate. There is no information on the positivity rate of cytology, the colposcopy rate among those screened positive and the cervical cancer detection rate. There is no proper referral system, and limited capacity for follow up of screened-positive women, lack of cyto-screeners and 11 colposcopy units only in the public health sector.

Women can be screened for breast cancer at primary health care, mainly through the Well Women Clinics and the Healthy Lifestyle Centres. In the public sector, women receive information and education on self-breast examination. The primary screening test is clinical-breast examination. At the Well Women Clinics, screening is organised among the same target group as for cervical cancer screening (aged 35 and 45), while at the Healthy Lifestyle Centres, screening is opportunistic, starting at age 35 (*Based on international evidence, clinical-breast examination is not recommended in women aged 35 because it will detect mostly benign lesions, increase the burden on the health system and increase anxiety among women).* If abnormality is detected, the woman is referred for mammography, ultrasound, fine needle aspiration cytology and referral for further investigations and treatment. However, there is a lack of mammographs, and they are mainly used for diagnostic mammography and not for screening purposes. Like the cervical cancer screening, the programme is measured only through participation rate, with no referral data and no cancer detection rate.

Thyroid cancer is screened by medical examination in women, at age 35 and 45 at the Well Women Clinics. Screening has been implemented since 2018 because thyroid cancer is one of the most common cancer in women. Data from the Ministry of Health show that mortality from thyroid cancer is very low and stable over time (*Based on international evidence, screening programme for thyroid cancer is not recommended because the mortality will not be reduced*). Early diagnosis of symptomatic women should be the preferred option. In addition, before implementing the screening programme through the Well Women Clinics, the determinants of thyroid cancers have to be examined to explain the continuous increase in incidence.

Early detection programmes are not implemented for other cancers. Prostate cancer screening is not promoted by the Ministry of Health and this follows the WHO recommendations. Colorectal cancer screening is also not promoted because of the limited diagnosis capacity.

In terms of cancer diagnosis, there is a variation in the availability of laboratory and pathology services. The number of essential pathology diagnostic services in relation to the level of health service requirements in each region is mismatched. Many pathology specimens are sent to tertiary care facilities for interpretation and this leads to these facilities being overworked and cause reporting delays, up to several weeks to months. The reporting system is manual, with hand-written results. Standardized report templates are not used. There is no electronic system for result reporting. None of the public sector laboratories are accredited by the Sri Lanka Accreditation Board. Each facility follows its own guidelines on specimen preparation and transport. Biological safety and environmental safety in laboratories and pathology services are lacking. Even basic safety measures such as eye wash stations are not available.

Cancer diagnostic imaging services have a general shortage of radiologists and lack of female radiographers (important issue for access). These are main obstacles for planning and effective implementation of national diagnostic services and major challenge to establish a breast cancer screening programme. There is a general shortage of nuclear medicine physicians, with only 3 physicians certified and available in the country. Radiology has a well-established postgraduate degree programme, but there is no postgraduate degree programme in nuclear medicine and no recognition of it as a separate medical speciality. There is no radiation protection programme

in radiology and nuclear medicine, with no use of personal dosimetry among the radiographers and radiologists. Long waiting list are noted (1 to 6 months) for CT scan, MRI, mammography and nuclear medicine procedures. Quality assurance programme is lacking, with no supervision and clinical audits.

All cancer treatment modalities are available in the country. It is estimated that 37% of patients are treated with surgery, 44% with radiotherapy and 51% with chemotherapy. The service delivery is based on a clinical oncology system, which includes same service providers for both medical oncology and radiation oncology services. Below is a summary description of the capacities and needs in each of the cancer treatment modality.

Medical oncology faces an important challenge of quality of the anti-cancer medications. Drugs are procured based on price, and this does not ensure quality. Sri Lanka does not have the ability to test drugs for quality. Approval of registration is done based on evidence provided by the drug supplier, rather than an independent test. No formal regional oncology guidelines exist to set standards of practice. Oncologists refer to using the United States' National Cancer Centres Network (NCCN) or similar international guidelines. However, these guidelines are not formally accepted or adapted to Sri Lanka's level of resources. All public-sector physicians, including specialists are employed full-time by the Ministry of Health. However, the salary is considered relatively low, and many physicians engage in private practice outside working hours. Private sector relies on medical officers/consultants who also work in the public sector. This may also lead to a real or perceived conflict of interest.

Local experts reported concerns regarding proper waste disposal of radioactive and biohazard material. Biohazard material is disinfected with a "bleach-like" substance and then poured down the drain. A general understanding of safe practices was understood, but there were no written guidelines, appointed safety officers, or formal training in safe handling practices and waste management.

Radiotherapy is available in both public and private facilities in Sri Lanka. Currently, there are 9 radiotherapy centres, 7 in the public and 2 in the private sector. The major radiotherapy centre is the Apeksha National Cancer Hospital in Colombo. Other 6 centres are located in the capital towns of the provinces. There is a plan to establish 3 more radiotherapy centres, making one radiotherapy centre in each province of Sri Lanka. The plan aims to have at least one linac and one HDR brachytherapy unit in each province and replace cobalt units with linacs. A modern linear accelerator can treat 500 patients in a year and Sri Lanka needs to operate minimum 24 external beam radiotherapy machines to cover needs. In long term (with estimated increases of number of cancer cases by 2040), the need for radiotherapy machines will increase to 33. Currently, there are 16 machines in use and 6 machines are in the phase of installation.

Since the number of current radiotherapy machines cannot cover the needs, there is a long waiting list especially at Apeksha Hospital and reduction is expected due to opening of new centres in the provinces and installation of new machines. An important concern is that most of the equipment for treatment planning is either unavailable or not operational. Maintenance and repair of the equipment is not regularly done in many centres leading to waiting times.

Radiation oncology is not a separate discipline in Sri Lanka. As already mentioned, clinical oncologists are certified to deliver both chemotherapy and radiotherapy. However, only those clinical oncologists employed at centres with radiotherapy capacity can perform radiation oncology. If we consider that a clinical oncologist dedicates half of working hours for radiotherapy, then Sri Lanka should have a total of 94 clinical oncologists. Current number is 55, insufficient to cover all patients needing radiotherapy.

The National Cancer Control Plan (2015) shows intent in developing and augmenting critical surgical subspecialties to support cancer treatment and control. One of the problems about the current system is that cancer surgeons get transferred from one centre to another every four years. This results in a mismatch of expertise and available infrastructure, inability to create teams and importantly, prevent quality research from being undertaken. While this is a problem in all areas of cancer treatment (radiation, surgical and medical oncology), this is particularly important for cancer surgery where this prevents complex procedures from being performed, and Centres of Excellence from being developed. For a country faced with over 20,000 new patients being diagnosed every year, there is a clear shortage of certified surgical oncologists along with availability of nurses and anaesthesiologists. On a conservative estimate, at least 35 more surgical and 6 more gynaecologic oncologists would be required within the next ten years. Another challenge in surgical oncology is that only 3 out of 9 provincial hospitals have separate dedicated surgical oncology operation units. A strong shift to dedicated operation theatres for cancer surgery would improve access to potentially curative treatment in a timely manner.

The training programme for surgical oncology is extensive, comprehensive and comparable with some of the best surgical oncology training programmes globally. The exposure to international centres treating cancers gives trainees an opportunity to learn from different work environments. However, continuous medical education could be improved with surgeons being funded by the government through academic funds to participate regularly in national and international meetings and workshops to enhance their skills and knowledge.

Paediatric oncologists and hemato-oncologists are also certified to deliver radiotherapy based on their training. Currently, there are only 2 certified paediatric oncologists, both at the Apeksha National Cancer Hospital. The annual number of childhood cancers is 600 to 700, which is beyond the current capacity. Although some clinical oncologists who have a special interest in paediatric oncology help in the management of these cases, there is still an urgent need for more certified paediatric oncologists. Main reasons for the low number are the long training period to be certified and the limited number of specialization slots. Principally all paediatric patients are sent to the Apeksha National Cancer Hospital to receive chemotherapy and radiotherapy, since this is the only paediatric cancer centre. This causes several problems including transport, accommodation and long-term follow-up of patients. As a result, some patients cannot access cancer care. Establishing paediatric cancer centres (units) in other large cities, preferably in Jaffna and Kandy, will improve access to paediatric cancer care.

There have been a lot of positive developments in the last 5 years in capacity building and initiation of palliative care services. Draft of the National Strategic Framework for Palliative Care has been developed and is currently available for review by relevant stakeholders. This

policy document is expected to be finalized in the next couple of months. Various policy and strategy documents on palliative care have been generated and many are being processed, but no action plan or timeline for action is available. Many tertiary teaching hospitals have started developing palliative care services, but there have been no initiatives at the secondary or primary health care, despite the stated policy intention of integrating palliative care into mainstream health care, with focus on primary health care.

With the available data on incidence and cancer stage, an estimate is that there are more than 15000 cancer patients in need of palliative care at any point of time. Currently, out of all cancer and non-cancer patients needing palliative care, less than 1% have access services. Civil society organisations have started taking a major role in establishment of supportive care services, hospices and home-based programmes. Most of their activities are linked to patient care in the public sector hospitals. However, there are no guidelines and standards available for these activities and they are not always aligned with the National Cancer Control Programme. In terms of access and availability of medications, opioids are available for medical use in theory, but there is no availability at the primary and secondary hospitals, with disruptions of supply that further limits accessibility. Training programmes at basic level need improvement.

In terms of radiation safety, the current legislation has elements of a national policy, however, the government has not yet established a separate document defining the national strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles in accordance to international standards. The government shall ensure that the regulatory body for radiation safety is effectively independent, in making decisions relating to protection and safety, of persons and organizations using or promoting the use of radiation and radioactive material, so that it is free from any undue influence by interested parties and from any conflicts of interest; and shall ensure that it has functional separation from entities having responsibilities or interests that could unduly influence its decision making. In terms of staffing and competence of the Regulatory Body, the IAEA team (mission conducted in 2018) observed that the training in medical uses of radiation is insufficient for the inspectors conducting inspections on radiotherapy facilities and activities.

Sri Lanka Atomic Energy Regulatory Council has developed and approved national radiological theft response code that is already being implemented, whereas, regulations on safety and security of radioactive material during manufacture, use and storage are presently in finalization and approval stage (expected in 2020). All Category 1 and 2 radioactive sources are under regulatory control and registered in the national source database. During the imPACT Review mission, the expert team was informed that all of the category 1 radioactive sources available in Sri Lanka (that includes radioactive sources used in medical settings) have been security wise upgraded through Sri Lanka–USDOE bilateral cooperation programme. In addition to health facilities, physical protection upgrades have also been implemented at central storage facility (for radioactive material) established and supervised by the Atomic Energy Board under the same project.

#### **Priority Recommendations**

#### National Cancer Control Planning and Governance

- Review and update the current National Cancer Control Plan (NCCP). As the structure and content of the document is still adequate and relevant, only an update (and not development of a new document) is recommended to be done by the NCCP Office staff (*specific recommendations on the NCCP review were provided in a separate document to the NCCP Director during the in-country mission*);
- The NCCP must establish clear priorities in all areas of cancer control in order to be realistic and implementable. The objectives and strategies should be followed by expected results (outputs) and SMART indicators;
- The NCCP and the corresponding action plan should be approved by the Secretary of Health after review and approval by the National Advisory Committee on Cancer Control. The National Advisory Committee (NAC) needs to update its composition and create Term of Reference (ToR), written and approved by the Secretary of Health. Its membership has to be expanded with the civil society sector, which is an essential stakeholder and an important contributor in the current cancer control response. The ToR should recognize the NAC as a high-level advisory body on cancer control;
- A Technical Advisory Committee (TAC) should be appointed to advice the National Advisory Committee (NAC) on all technical issues regarding cancer control. For example, to develop/review the national radiotherapy plan; the national essential medicines list and its procurement; the human resources development plan; the quality assurance programme for different areas of cancer diagnosis and treatment services; the national adapted guidelines for cancer management; the national policy/strategy for early detection of cancer; the support to the non-communicable disease (NCD) programme to reduce common risk factors; the national policy and guidelines for palliative care. Members should be representing prevention, early detection, diagnosis, treatment, palliative care, cancer surveillance, professional societies, training and education institutions, and civil society.

### [WHO should be approached for assistance in this area.]

### **Cancer Registry and Surveillance**

- Develop a legal framework to enact cancer as a notifiable disease. In addition to hospitals, consider including other institutions in possession of cancer related data e.g. health insurance agencies, hospitals for indigenous medicine, cancer screening programmes and the vital statistics office. Ensure that the legal framework captures linkages, data exchange and improvements of existing mortality statistics (through the work of the death registrars and the hospital mortality registry) relevant to cancer data;
- A Cancer Registry Technical Committee, as a sub-committee of the National Advisory Committee (NAC) for cancer control should be established, comprised of stakeholders that will oversee and provide technical guidance to the future developments of the national cancer registry system;

• Considering heavy backlog of data analysis, it is recommended to start with data analysis of the most recent years (2018 and onward). Data from the last 3 years, especially from pathology laboratories combined with other readily available representative data from teaching, provincial and district hospitals can be utilized to estimate the burden of new cancers for Sri Lanka. It will be helpful if intermediate reports are prepared every 6 months to monitor the data in-flow and other processes.

### [IARC should be approached for assistance in this area.]

### Prevention

- Strengthen tobacco control enforcement measures (targeting betel quid) by increasing the role of enforcement organizations and entities (medical officers, public health inspectors;
- Modify the existing legislation of the National Authority on Tobacco and Alcohol (NATA) Act to strengthen control over tobacco mixture products. Further, introduce regulations on areca nut and other carcinogenic products;
- Increase taxes on all types of tobacco products. Unaffordability of alcohol and tobacco products is the public health measure that has proven effective.

[IARC and WHO should be approached for assistance in this area.]

### **Early Detection**

- Strengthen the referral-up and referral-back system of screened positive cases or early diagnosed cases (*NCCP through the district and provincial director of health services to provide guidance e.g. specific forms to doctors at secondary and tertiary levels*). As part of these activities, consider decreasing the number of visits prior final diagnosis for oral, cervical and breast cancer and link the screening health care to diagnosis health care level;
- Update screening guidelines with national standards for screening programme performance indicators and ensure regular monitoring of these indicators;
- Analyse the results of the pilot study on cervical cancer screening by HPV-DNA testing in terms of affordability and sustainability before scaling up the programme. The cost-benefit analysis is also needed (anticipated collaboration with UNFPA in 2020);
- Consider doing clinical-breast examination (CBE) in women aged 45 and over and stop doing CBE in women aged 35, because it will detect mostly benign lesions that will need to be referred for mammography, increase the financial burden on the health system and increase anxiety among women;
- Stop screening systematically 35- and 45-year old women at the Well Women Clinics (WWCs) for thyroid cancer. Examine the determinants of thyroid cancers to explain the continuous increased incidence that seems not related to screening activity, before implementing screening programme. Screening for thyroid cancer will not decrease mortality from thyroid cancer (aim of screening), moreover, it will increase anxiety in screened positive women and increase the burden on the health system;
- Based on the WHO recommendations, prostate cancer screening programme should not be introduced and any practice to screen asymptomatic men for prostate cancer using PSA test

should be discontinued. Also, screening for colorectal cancer should not be introduced because of the shortage of endoscopy facilities and adequate number of human resources.

[For matters related to diagnostic imaging IAEA should be approached; for others IARC and WHO should be approached for assistance]

### Diagnosis (Pathology and Laboratory Services)

- Establish infrastructure and mechanisms for timely testing and reporting of results to patient's treating physician. This may involve implementing an electronic medical record system for pathology and standardization of pathology reports. The College of American Pathology, the Royal College of Pathologists, the National Cancer Grid of India and several other organizations have template (<u>https://www.cap.org/protocols-and-guidelines/cancer-reporting-tools/cancer-protocol-templates</u>) reports for their own use that may be modified for use in Sri Lanka;
- Establish standard operation procedures (SOPs) for laboratory safety and waste disposal. Appoint safety officers for each laboratory. This is a basic requirement for any laboratory;
- Develop a Clinical Advisory committee (*could be a technical sub-committee under the auspices of the National Advisory Committee on Cancer Control*) that includes consultant haematologists, histopathologists, and chemical pathologists nominated by the respective colleges, headed by the Deputy Director General Laboratory Services and in addition Director Laboratory Service, Provincial Directors of Health Services when relevant. This committee can assist in allocation of human resources, supplies and necessary funding.

### [WHO should be approached for assistance in this area]

#### Diagnosis (Diagnostic Imaging and Nuclear Medicine)

- Initiate formulation of a workforce development plan with support from the IAEA to identify needs for number and profile of medical and para-medical staff;
- Enforce the knowledge and practice of radiation protection in diagnostic imaging departments with the support of the IAEA, by providing training courses covering this field. Ensure continuous education in this field, as compulsory to licence and re-licence practice;
- Initiate post-graduate degree programme in nuclear medicine by using the IAEA curriculum published recently, in collaboration with the University of Peradeniya and the Postgraduate Institute of Medicine at the University of Colombo. As part of it, ensure professional qualification in nuclear medicine for radiologists;
- Initiate establishment of a central radio-pharmacy to decrease cost and start new examinations by making most of the radiotracers available and affordable, provided that the national legislation allows the internal transportation of radioactive materials. For example, in Colombo they use every week 5 generators of Technetium for 5 different centres (1 generator per centre). With central radio-pharmacy, the number of generators can be decreased to 2 and even 1 generator weekly, to cover needs of all centres;

- For radioiodine treatment, develop national guideline in collaboration with the IAEA and local atomic energy commission to apply latest recommendations which will increase the number of treated patients and decrease the waiting list time significantly;
- Develop training programme for radio-pharmacists, with support from the IAEA to ensure adequate professional qualification and competencies.

#### [IAEA should be approached for assistance in this area]

### **Treatment (Medical Oncology)**

- Establish a mechanism to assure adequate supply of quality oncology drugs. Supporting data collection in quantifying and understanding the reasons for these drug shortages is a critical first step in coming up with a long-term solution for this problem. This may also involve instating a review panel to prioritize the anti-cancer medications that need to be available continuously and predict the usage of these drugs and determine adequate reserve levels. Prioritization of drugs to be based on both efficacy as well as cost analysis. Consider limiting the purchase of drugs to those who have been certified by either the US FDA or EMA to ensure quality. Studies show that patients who have excessive treatment delays or incomplete treatment (< 80% of planned drug therapy) have worse survival;
- Strengthen and clarify the referral pathway for cancer patients. Establish referral processes for timely evaluation of patients who need additional diagnostic procedures (in cluding colposcopy, diagnostic mammography, endoscopies, biopsies, and radiographic procedures). Standardise protocols, pathways, and communication formats for providers;
- Guidelines for the treatment of the common types of cancer should be established and standardized. International guidelines exist which could be adopted. The NCCN has developed resource stratified guidelines which could be adopted for use in the various regions within Sri Lanka that have different levels of resources;
- Review and improve safety and waste disposal procedures in the pathology, chemotherapy;
- Overcrowding at the Apeksha Hospital could be decreased by shifting the administration of chemotherapy to the outpatient setting. Successful models exist where patients who travel to get chemotherapy may get chemotherapy as an outpatient and the use low-cost housing overnight as opposed to using an inpatient bed.

#### [WHO should be approached for assistance in this area]

### **Treatment (Radiation Oncology)**

- Collaborate with the IAEA for training of clinical oncologists, medical physicists and RTTs to enhance their capacity on the transition from 2D to 3D radiotherapy including IMRT;
- Share the current development and procurement plan with the IAEA and the Sri Lanka College of Oncologists for review, and closely collaborate with these partners in planning for and establishment of the new radiotherapy centres, as well as upgrade of existing.

### [IAEA should be approached for assistance in this area]

### **Treatment (Surgical Oncology)**

- Adapt existing resource-stratified evidence-based management guidelines for treatment of patients with cancer. The Indian National Cancer Grid guidelines may be adapted without need to develop separate guidelines;
- Increase dedicated operating theatre slots for cancer surgery in all major centres treating cancer (including all hospitals with surgical oncology units);
- Ensure mandatory review of patients in multidisciplinary tumour boards and regular audits with monthly Mortality and Morbidity (M&M) meetings.

### [WHO should be approached for assistance in this area]

### Treatment (Paediatric Oncology)

- Collaborate with the International Society of Paediatric Oncology, WHO and IAEA for training of paediatric oncologists and review of their current formal education programme;
- Develop a comprehensive long-term paediatric cancer policy;
- Establish paediatric oncology centres in other main cities, preferably in Jaffna and Kandy.

[For radiotherapy related matters IAEA should be approached for assistance; for other areas WHO should be approached]

### **Palliative Care**

- National Palliative Care Strategy should be finalised and endorsed. An action plan integrating palliative care into mainstream health care, with emphasis on primary health care to be generated as a matter of priority. A technical committee under the National Cancer Control Committee can be appointed for this assignment;
- Consolidation and expansion of the existing palliative care services in the Government sector to be done. This will mean allotment of regular permanent staff, basic budgetary provisions and ensuring uninterrupted supply of necessary medicines including opioids. This recommendation can be operationalized through:
  - An orientation programme for oncologists and other consultants to ensure that they play a more active role in palliative care in the hospital settings;
  - Under the auspice of the NCCP office, conduct a national workshop with key stakeholders to review the existing procurement and supply process of medicines and associated regulations;
  - Develop an opioid drug procurement calendar in the hospitals to better estimate usage of opioid analgesics and place orders in time to ensure uninterrupted supply. An annual estimate can be made based on the estimated number of incurable cancer patients expected to register each year. With an average of 60mg/day consumption per patient and average of 100 days of analgesic support a year, 6 g of oral morphine will be needed per patient registered. If the expected number of patients next year is 100, the amount of oral morphine (or equivalents) to be ordered will be 600 g.
- Guidelines and standards for inpatient services/hospices and home-based care services to be urgently established. An accreditation system for civil society organizations managing

palliative care services to be established based on compliance to these guidelines and standards. Accredited services to be linked to the Government hospitals in the region for mutual support and complementing services. Such a system of accreditation-based collaboration will ensure accountability and quality of services in the civil society sector.

[For palliative radiotherapy IAEA should be approached for assistance; for other areas WHO should be approached]

#### **Radiation Safety and Security of Radioactive Material**

• The Radiation Safety and Security Regulations should be finalized and promulgated on a priority basis;

[IAEA should be approached for assistance in this area]

### 1. The Review

### 1.1. Purpose

At the request of the Government of the Democratic Socialist Republic of Sri Lanka (May 2019), an imPACT Review was conducted from July to November 2019, as a collaborative effort of the International Atomic Energy Agency (IAEA), the World Health Organization (WHO) and the International Agency for Research on Cancer (IARC). As part of the Review, an in-country mission was carried out from 28 October to 02 November 2019. The imPACT Review had the following objectives:

- Assess national cancer control capacities (government partners; civil society sector; professional societies and academia) and needs in the areas of cancer control planning, cancer registration, prevention, early detection, diagnosis and treatment, palliative care;
- Assess capacities and needs for the safe and effective implementation of radiation medicine projects, as a component of national comprehensive cancer control programmes;
- Assess capacities and needs related to the national regulatory infrastructure for radiation safety and security, with focus on applications of ionising radiation in health care settings and use of radioactive sources; and
- Identify opportunities for partnerships in cancer control.

# 1.2. Review Team Composition

### International Atomic Energy Agency

- Ms Geraldine Arias De Goebl, Review Leader, Division of Programme of Action for Cancer Therapy
- Mr Igor Veljkovikj, Review Coordinator, Division of Programme of Action for Cancer Therapy
- o Mr Waseem Muhamad, Nuclear Security Officer, Division of Nuclear Security

### World Health Organization, Country Office in Sri Lanka

o Dr Nalika Gunawardena

### World Health Organization, Regional Office for South-East Asia

o Dr Dorji Gampo

#### **External Experts**

- o Dr Rolando Camacho, Cancer Control Planning, nominated by IAEA and WHO
- o Dr Swaminathan Rajaraman, Cancer Registration and Surveillance, nominated by IARC
- Dr Catherine Sauvaget, Prevention and Early Detection, nominated by IARC
- Dr Mohamad Bahjat Haidar, Diagnostic Imaging, nominated by IAEA
- o Dr Yavuz Anacak, Cancer Treatment, including Paediatric Oncology, nominated by IAEA
- Dr, C S Pramesh, Surgical Oncology, nominated by WHO
- o Dr Jo Anne Zujewski, Medical Oncology and Pathology, nominated by WHO
- Dr Suresh Kumar, Palliative Care, nominated by WHO

Area of expertise	Name of national expert	Designation
National Cancer control planning & coordination	Dr.Champika Wickramasingha	Deputy Director General (NCD)
	Dr. Janaki Vidanapathirana	Director, National Cancer Control Programme (NCCP)
	Dr. Sudath Samaraweera	Former Director, National Cancer Control Programme
Cancer registry & surveillance	Dr.Suraj Perera	Consultant Community Physician (CCP), NCCP
Prevention & early detection	Dr.Udaya Usgodaarachchi	Consultant in Community Dentistry /NCCP
	Dr.Loshan Moonasingha	CCP – Family Health Bureau
Diagnostic imaging & nuclear medicine	Dr. Uditha Kumarasena	Consultant Radiologist, Apeksha hospital
Pathology & laboratory medicine	Dr.Priyangi Amarabandu	Consultant Pathologist, Apeksha hospital
	Dr.Lalindra Goonaratne	Senior Lecturer in Haematology
	Dr.Rajitha Samarasingha	Consultant Chemical Pathologist, Apeksha hospital
Surgical oncology	Dr.Jayamal Ariyaratne	Consultant Oncosurgeon, TH Karapitiya
Medical oncology & radiation oncology	Dr. Yasantha Ariyaratne	Consultant Oncologist
Paediatric oncology	Dr.Sanjeewa Gunasekara	Consultant Paediatric Oncologist, Apeksha hospital
Palliative care	Dr.Sujeewa Weerasingha	Consultant Oncologist, Apeksha hospital
Radiation safety and security infrastructure	Mr. K.V. Athula Wijekumara	Chief Medical Physicist, Apeksha hospital

# Ministry of Health, Nutrition and Indigenous Medicine Designated Team of Experts

### 2. Review Findings and Recommendations

### 2.1. Health System Overview

#### **Organization and Service Delivery**

Healthcare in Sri Lanka is delivered via a hybrid system, mainly composed of public and private sector, and a minor representation of non-profit sector (*for details see Diagram 1*). Allopathic medicine is predominant compared to indigenous traditional medicine, both provided through a network of preventive and curative health services.

Preventive health services are organized through the Medical Offices of Health (MOH), with a catchment area of 60,000-100,000 people. They provide a range of services relevant to cancer control such as immunization, oral health, environmental health, occupational health and screening for cervical and breast cancers delivered though the Well Woman Clinics (WWC).

Provision of curative healthcare is carried out through a network of hospitals:

- At secondary level, seventy-one base hospitals (BH) providing at least four main specialties (also relevant to cancer care): Internal Medicine, Paediatrics, Obstetrics and Gynaecology, and Surgery. Majority of these hospitals are funded and managed by provincial and district health authorities;
- At tertiary level, National Hospital of Sri Lanka, twenty-three teaching hospitals (TH), two provincial general hospitals (PH), nineteen district general hospitals (DH) and highly specialized hospitals such as the Maharagama Cancer (Apeksha) Hospital, which plays a role as a cancer centre of excellence. All these hospitals are funded and managed by the Ministry of Health and Indigenous Medicine.

In the private sector, there are three main groups of providers: hospitals, clinics and diagnostic services. Hospitals and clinics rely heavily on health professionals working in the public sector, as dual clinical practice is allowed. In terms of cancer management, there is a single dedicated private cancer hospital based in Colombo.<sup>12</sup>

The public sector model offers free services at all levels of health care. 90% of in-patient care is delivered within the public sector. Outpatient care is delivered more equally between the public and private health sector. Although cancer-specific data are not available, it is assumed that a similar distribution exists. The main regular users of the private sector are the better off population. It is currently undergoing significant expansion across all levels of health care.

An important challenge of Sri Lanka health system pertaining to cancer care, are the inequities in availability of services across provinces. Geographical access is a constraint for patients living outside major health centres and have to travel long distances to access health care.<sup>3</sup>

<sup>&</sup>lt;sup>1</sup> Ministry of Health, Nutrition and Indigenous Medicine (2019), Action Plan 2019

<sup>&</sup>lt;sup>2</sup> Ministry of Health, Nutrition and Indigenous Medicine (2019), Essential Health Services Package

<sup>&</sup>lt;sup>3</sup> Sanjeeva Gunasekera et al. (2019), Delivery of Cancer Care in Sri Lanka. <u>https://doi.org/10.1016/j.jcpo.2018.10.001</u>



### Diagram 1. Description of Sri Lanka Health System (MoHNIM, 2019)

### Governance of the Health System

The Ministry of Health, Nutrition and Indigenous Medicine is primarily responsible for the provision of comprehensive healthcare in the public sector. It has the following key duties and functions:

- Formulation of policies, programmes and projects, monitoring and evaluation with regards health, nutrition and indigenous medicine
- Formulation of policies and standards required for public health services
- Regulation and supervision of the quality, standards and pricing of private hospitals and medical centres
- Regulation and supervision of charitable medical institutions
- Adoption of measures for the control of communicable and non-communicable diseases
- Management of hospitals and staff employed, other than hospitals (most of the basehospitals), where management is decentralized to provincial and district health authorities
- Expansion of training opportunities for health professionals

The Ministry of Health is also responsible to issues related to production, import and distribution of medications. The National Medicines Regulatory Authority (NMRA), under the purview of the Ministry of Health is responsible for regulating medicines (including prices), medical devices, clinical trials and cosmetics. The Ministry of Higher Education is responsible for the training of health professionals.<sup>45</sup>

<sup>&</sup>lt;sup>4</sup> Sanjeeva Gunasekera et al. (2019), Delivery of Cancer Care in Sri Lanka. <u>https://doi.org/10.1016/j.jcpo.2018.10.001</u>

<sup>&</sup>lt;sup>5</sup> Ministry of Health, Nutrition and Indigenous Medicine (2019), Action Plan 2019

### **Health Financing**

The public health sector is predominantly financed through general revenue taxation and the private health sector has blended financing from private insurance, enterprise direct payments, enterprise insurance and out-of-pocket payments. Donor funding is to great extent streamlined through the government sector and to less extent to the non-profit organizations.<sup>6</sup>

Health expenditure as a share of gross domestic product has significantly decreased, especially between 2010 to 2015, being around 3% of the GDP in 2015. This was mostly driven by having public spending on health growing slower than the overall economy. Latest available data from 2015 show that general government spending on health is at 8%, while out-of-pocket expenditure as a share of the health expenditure is around 38%. **Table 1** presents summary of health financing data.

Table 1. Summary of Health Expenditure in Sri Lanka, 20157					
Health expenditure as a share (%) of GDP	2.97%				
General Government Health Expenditure, as % of General Government Expenditure	8 %				
Out-of-pocket expenditure as % of health expenditure	38.43%				
Health expenditure per capita (in US\$)	118				

### Health Workforce

According to the Ministry of Health and Indigenous Medicine (MoHIM), there were 140,000 workers in the public sector in 2015, more than half working for tertiary level institutions. The profile of the health professionals is composed of Medical Officers, Nurses, Midwives and Public Health Inspectors, as well as Dental Surgeons, with the addition of staff specialised in support services (laboratory; pharmacy etc.)<sup>8</sup>

Sri Lankan oncology services are provided by clinical oncologists. There are currently 49 board certified oncologists practicing, 44 work in the public sector and 5 in the private sector. In addition, there are 2 paediatric oncologists. Although clinical oncologists are certified to practice medical oncology and radiation oncology, nearly 1/3 of oncologists in Sri Lanka do not have access to radiotherapy facilities in the public sector. Paediatric oncology and haemato-oncology are relatively new sub specialities in Sri Lanka. Currently, there are 18 board certified onco-surgeons and 6 gynae-oncologists in practice.

The institution responsible for post-graduate education in Sri Lanka is Post Graduate Institute of Medicine at the University of Colombo. This is fully funded by the Ministry of Health and Indigenous Medicine.<sup>9</sup>

<sup>&</sup>lt;sup>6</sup> Institute for Health Policy; Sri Lanka Health Accounts: National Health Expenditure 1990-2014

<sup>&</sup>lt;sup>7</sup> WHO 2017 https://apps.who.int/iris/bitstream/handle/10665/259644/HFP-SRL.pdf?sequence=1&isAllowed=y

<sup>&</sup>lt;sup>8</sup> Ministry of Health, Nutrition and Indigenous Medicine (2019), Essential Health Services Package

<sup>&</sup>lt;sup>9</sup> Sanjeeva Gunasekera et al. (2019), Delivery of Cancer Care in Sri Lanka. <u>https://doi.org/10.1016/j.jcpo.2018.10.001</u>

#### **Health Information System**

The current health information system consists of inputs provided by public sector health providers. As of 2016, the information sub-systems have been developed. They consist of curative/hospital-based information system, preventive health information system, population census, civil and vital registration system, as well as routine population-based health surveys.<sup>10</sup>

Since 1980, the National Cancer Control Programme (NCCP) covers data for all cancers treated at the national cancer treatment centers and data from the major private and government hospitals and pathology laboratories. The NCCP is also responsible for maintaining the Sri Lanka Cancer Registry (SLCR).

#### Access to Essential Medicines and Technology

In Sri Lanka, the National Medicines Regulatory Authority (NMRA), under the purview of the Ministry of Health, Nutrition and Indigenous Medicine, plays a leading role in protecting and improving public health products available and ensuring they meet standards of safety, quality and efficiency. NMRA is responsible for regulating medicines, medical devices and clinical trials. The National Medicine Quality Assurance Laboratory functions under the purview of the NMRA and ensures the quality of medical products. Its work includes needs assessment for availability of a medical product; ensures medical products are appropriately manufactured, stored, distributed and dispensed; and regulates the prices of medical products.<sup>11</sup>

### 2.2. Burden of Disease

According to the MoHNIM Annual Health Bulletin from 2014, cancer was the second leading cause of hospital deaths after ischaemic heart disease, with 24 mortality cases per 100,000 population. In the same year (2014), the Sri Lanka Cancer Registry (SLCR) reported 23,105 new cancer cases, with an Age-Standardized Rate (ASR) of 98.1 per 100,000 population. The most common cancers in 2014 were: **among men** - oral cavity (ASR:15.6), lung (ASR: 9.6), oesophagus (ASR: 7.7), colorectum (ASR: 6.9) and prostate (ASR: 6.7); **among women** - breast (ASR: 24.3), thyroid (ASR: 11.3), cervix (ASR: 8.2), ovary (ASR: 7.2) and colorectum (ASR: 6.9). 95% of the cases were diagnosed through microscope diagnosis, which is too high and suggests possible missing data for more-advanced stages of cancers. In addition, 15% of cases lacked data on residence.

GLOBOCAN (2018) data estimates that each year 23 530 new cases and 14 013 deaths are recorded. The most common cancers among women were breast, cervix, thyroid and ovary. In men, the most common cancers are oral cavity, lung, oesophagus and colorectal.<sup>12</sup> The rates

<sup>&</sup>lt;sup>10</sup> Health.gov.lk. (2015). The National Policy on Health Information. [online] Available at: http://www.health.gov.lk/enWeb/Pub\_Opi/National%20Health%20Information%20Policy\_English\_v\_14\_04\_2016.pdf [Accessed 18 Oct. 2019].

<sup>[</sup>Accessed 18 Oct. 2019]. <sup>11</sup>About NMRA [Internet]. Nmra.gov.lk. 2019 [cited 18 October 2019]. Available from: https://nmra.gov.lk/index.php?option=com\_content&view=article&id=90&Itemid=168&lang=en

<sup>&</sup>lt;sup>12</sup> Sri Lanka [Internet]. Gco.iarc.fr. 2018 [cited 18 October 2019]. Available from: https://gco.iarc.fr/today/data/factsheets/populations/144-sri-lanka-fact-sheets.pdf

are similar with the state cancer registry of Tamil Nadu in India, but much lower than observed in majority of Thailand and other South-East Asian nations [CI5, Vol XI, 2017].

Number of new cancer cases per year: 23 530							
	Mal	es		Females			
Cancer Site	No. of cases	% of cancers	ASR (W)*	Cancer Site	No. of cases	% of cancers	ASR (W)*
Lip, oral cavity	1576	14.8%	12.3	Breast	3091	24.0%	22.2
Lung	1065	10.0%	8.3	Cervix Uteri	1136	8.8%	7.8
Oesophagus	771	7.2%	6.0	Thyroid	1 043	8.1%	8.5
Colorectum	734	7.0%	5.8	Ovary	856	6.6%	6.2
Stomach	589	5.5%	4.6	Colorectum	707	5.5%	4.7
Other	5910	55.5%	61.0	Other	6052	47.0%	41.9
Total	10 645	100%	85.7	Total	12 885	100%	91.3

Table 2. (	Cancer I	ncidence and	Mortality in	Sri Lanka,	, <b>2018</b> <sup>13</sup>
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Number of deaths per year: 14 013						
	Males		Females			
Cancer Site	No. of cases	ASR (W)*	Cancer Site	No. of cases	ASR (W)*	
Lip, oral cavity	721	5.6	Breast	1183	8.1	
Lung	883	6.8	Cervix Uteri	643	4.2	
Oesophagus	622	4.8	Thyroid	111	0.8	
Colorectum	518	4.0	Ovary	516	3.6	
Stomach	469	3.6	Colorectum	450	2.9	
Other	3915	31.9	Other	3982	27.0	
Total	7128	56.7	Total	6885	46.6	

<sup>&</sup>lt;sup>13</sup>Cancer tomorrow [Internet]. Gco.iarc.fr. 2019 [cited 18 October 2019]. Available from: http://gco.iarc.fr/tomorrow/graphic-line?type=1&population=900&mode=population&sex=0&cancer=39&age\_group=value&apc\_female=0

### 2.3. National Cancer Control Planning and Governance

#### Development, Review and Implementation of a National Cancer Control Plan (NCCP)

The current NCCP (2015) is well structured and its purpose, guiding principles and scope are both relevant and adequate. The introduction of the document covers most relevant information related to national cancer burden. However, data presented are only from the national Sri Lanka Cancer Registry. There is no reference to GLOBOCAN estimates, which will allow data to be compared at regional and international level.

As a policy document, this version of the NCCP includes all areas of cancer control, although it seems that in practice the NCCP is more focused on cancer registration, prevention, early detection and palliative care, relaying the planning and coordination of diagnostic and treatment services to other directorates in the Ministry of Health (MoHNIM).

In general, the approach reflected in the NCCP is updated and technically sound; while it comprehensively lists out all aspects of cancer control, lack of prioritization of action points is a weakness. In some cases, the objectives and strategies are not realistic and not defined in a way that could be implementable and feasible.

There are two important sections of the strategy that are not included in the current NCCP: the expected results and indicators. Those sections are crucial for any NCCP. Developing them helps a lot to focus and to define priorities, and it helps to develop a more pragmatic strategy.

The NCCP strategic document includes seven objectives and each of them include a number of strategic actions. All the seven objectives are sound and well defined, covering all topics of cancer control and in accordance with WHO recommendations. Objectives are presented in the order of cancer control continuum, which is the standard way to do it; however, the strategic actions are not ordered by priority. As noted above, all the seven objectives lack the sections on expected results and indicators for the strategic actions. Suggestions on the wording of some objectives and priorities in the strategic actions are included in a separate report (NCCP detailed review) provided to the Ministry of Health team during the in-country mission.

Another important missing component of the NCCP is the action plan. This should include all activities needed to be implemented in each of the cancer control strategies, the responsible institutions to implement them, timeframe, budget and budget source, and indicators to monitor and evaluate the actions.

#### National Cancer Control Coordination

The established National Advisory Committee (NAC) is an important platform to guide the Ministry of Health in different areas of cancer control. All stakeholders are represented and probably the only one lacking representation is the civil society. The NCCP has not created an executive Technical Advisory Committee with representation of all areas of cancer control that can provide not only their expertise but assist in the development plans of their respective areas.

The National Cancer Control Programme Office (NCCP Office) is a great opportunity for planning cancer control and for the coordination of implementation at national level. There is no detailed information on the composition, role and performance of the NCCP Office. The Office has a web page with information mainly on policy documents, cancer information data, several educational materials for patients and population on most relevant cancers sites, as well as several policy documents and materials on palliative care (<u>http://www.nccp.health.gov.lk/</u>)

The NCCP states that at provincial level there are "provincial committees of cancer prevention and control that will function as the provincial focal point to implement cancer control activities in each province". There is no definition on their composition, scope and way of work. It was not possible to assess whether they have an action plan or how the National Office coordinates their work and measures their performance. In the same way, the NCCP states that at district level, there are "district cancer control committees". Same questions as for the provincial committees need to be answered to understand how they operate.

Finally, the document states that the "NCCP Directorate in the Ministry of Health will monitor and evaluate cancer control and prevention activities at national level". Without an action plan of the NCCP and defined indicators, it is not possible to measure progress and evaluate cancer control activities. In the same way, regional/district level cancer control activities can't be monitored by the Provincial/District Cancer Control Committees.

The Ministry of Health (MoHNIM) existing health policies constitute an opportunity for the NCCP, in terms of coordination, synergies and resource sharing. For example, the National Strategic Framework for Development of Health Services (2016-2025) identifies challenges and corresponding strategies relevant to non-communicable diseases and cancer control. (http://www.nationalplanningcycles.org/sites/default/files/planning\_cycle\_repository/sri\_lank a/national\_strategic\_framework\_.pdf). Aligning and linking the cancer control strategy to the overall healthcare policy of the MoHNIM is crucial.

### **Financing National Cancer Control Plan**

As there is no action plan for the NCCP, there is no budget allocated and no financing sources identified. The NCCP has not developed a strategy for resource mobilization on cancer control to identify and potentially leverage additional funding from donors, development partners and the private sector, beyond the regular financing that comes from the Ministry of Health and the provincial authorities.

### Recommendations

### Short-term (6 to 12 months)

### Development, Review and Implementation of a National Cancer Control Plan (NCCP)

• Review and update the current NCCP. As the structure and content of the document is still adequate and relevant, it is recommended to be done by the NCCP Office staff (*specific recommendations on the NCCP review were provided in a separate document to the NCCP Director during the in-country mission*);

- The NCCP must establish clear priorities in all areas of cancer control in order to be realistic and implementable. The objectives and strategies should be followed by expected results (outputs) and SMART indicators;
- The NCCP and the corresponding action plan should be approved by the Secretary of Health after review and approval by the National Advisory Committee on Cancer Control.

#### National Cancer Control Coordination

- The National Advisory Committee (NAC) needs to update its composition and create Term of Reference (ToR), written and approved by the Secretary of Health. Its membership has to be expanded with the civil society sector, which is an essential stakeholder and an important contributor in the current cancer control response. The ToR should recognize the NAC as a high-level advisory body on cancer control;
- Ensure NAC quarterly meetings with the participation of relevant specialists in all areas of cancer control (including private sector and civil society representatives) to review the progress on cancer control. The NCCP Office should present a report on the progress on cancer control activities in Sri Lanka during these quarterly meetings;
- A Technical Advisory Committee (TAC) should be appointed to advice the National Advisory Committee (NAC) on all technical issues regarding cancer control. For example, to develop/review the national radiotherapy plan; the national essential medicines list and its procurement; the human resources development plan; the quality assurance programme for different areas of cancer diagnosis and treatment services; the national adapted guidelines for cancer management; the national policy/strategy for early detection of cancer; the support to the NCD programme to reduce common risk factors; the national policy and guidelines for palliative care. Members should be representing prevention, early detection, diagnosis, treatment, palliative care, cancer surveillance, professional societies, training and education institutions, and civil society. This committee should meet on regular basis (quarterly). Individual meetings between the Director of the NCCP and particular members could also be planned on ad hoc basis;
- Each member of the Technical Advisory Committee should have a Technical Group (TG) for the area of cancer control they represent to produce area-specific recommendations. A recommended structure and examples of tasks to be developed by the TG are included in in a separate document to the NCCP Director during the in-country mission;
- Terms of Reference for the TAC and TG should be written and signed by all members. Both, the TAC and the TG should be officially appointed by the Secretary of Health;
- Review the composition and tasks of the NCCP Office staff, to enable better coordination with national health experts and health providers on technical issues. The staff at this office should be focused on coordination of activities (i.e. to provide a platform and facilitate linkages between the different members of the technical groups and the TAC), and not involved in implementation of activities.

### **Financing National Cancer Control Plan**

- The NCCP should have a costed action plan with defined priorities, responsible partners for implementation, identified sources of financing and a reasonable timeframe;
- Consider requesting WHO guidance regarding costing of the action plan;

### Medium-term (12 to 36 months):

### Development, Review and Implementation of a National Cancer Control Plan (NCCP)

- Discuss on annual basis the progress in implementation of the NCCP action plan, by:
  - Updating progress in implementation of relevant imPACT Review recommendations
  - Monitor indicators under each objective and strategic actions
  - Review, reprioritize and update the NCCP action plan

### National Cancer Control Coordination

- Ensure the National Advisory Committee (NAC) meets on quarterly basis and the NCCP Office presents the progress report on cancer control situation in the country;
- Ensure the Technical Advisory Committee (TAC) meets on regular basis (quarterly) and each of the Technical Groups (TG) produce development plans in specific areas of specific cancer control (as guided by the NAC and TAC);
- Include the review of the Terms of Reference of the NCCP Office staff on annual basis to improve efficiency and best utilization of the human resources.

### **Financing National Cancer Control Plan**

- Based on the NCCP action plan, develop a strategy for resource mobilization and initiate outreach to donor, development partners and the private sector to leverage financial and partnership support;
- Ensure financial coverage for at least the priority actions identified in the NCCP;

### Development, Review and Implementation of a National Cancer Control Plan (NCCP)

- Organize and implement an "Evaluation of the NCCP Strategy and Action Plan" on fiveyear basis
- Review the NCCP and Action Plan based on the five-year evaluation, available scientific evidence and availability of resources of the country.

#### 2.4. Registration and Surveillance

#### **Cancer Registry System Overview**

Sri Lanka has two major population-based cancer registries: the Sri Lanka Cancer Registry (SLCR) and the Colombo District Cancer Registry (Colombo PBCR). Establishment of a new population-based cancer registry covering the Northern Province has been initiated. The country has one operational hospital-based cancer registry, which is located at the Apeksha National Cancer Hospital. Some provincial hospitals, like the Karapitiya Teaching Hospital, have medical records and existing information system adequate for a cancer registry.

### **Cancer Registry Reporting**

In 2014, the Sri Lanka Cancer Registry (SLCR) reported 23,105 new cancer cases, with an Age-Standardized Rate (ASR) of 98.1 per 100,000 population. The most common cancers among men were: oral cavity (ASR:15.6), lung (ASR: 9.6), oesophagus (ASR: 7.7), colorectum (ASR: 6.9) and prostate (ASR: 6.7); and among women were: breast (ASR: 24.3), thyroid (ASR: 11.3), cervix (ASR: 8.2), ovary (ASR: 7.2) and colorectum (ASR: 6.9). This is an increasing trend in both the absolute number and ASR compared to 2011. However, this increasing trend could also be a result of expanding the number of sources providing cancer registry data and improving the coverage of the Sri Lanka Cancer Registry.

Latest published report from the Sri Lanka Cancer Registry is from 2011. According to the report, 95% of the cases were diagnosed through microscope diagnosis, which is too high and suggests possible missing data for more-advanced stages of cancers. 4.4% of all cancers were of unknown primary site. 15% of cases lacked data on residence and this is mainly for data coming from the pathology laboratories. To overcome this information gap, the reporting forms for tumour specimen should include the variable on location or district of usual residence.

### **Cancer Registry Legal Framework**

Cancer is not a notifiable disease in Sri Lanka. With the purpose to improve reporting, a circular was issued by the Ministry of Health (MoHIM) in 2015, to guide the cancer treatment centres to provide cancer data using the National Cancer Surveillance Form (NCSF). The data are gathered into a centralized database (NCCPSL). In addition, there is the Cancer Registry Form (CRF) mainly used by the pathology laboratories and Oral and Maxillofacial (OMF) units for oral cancer screening. Cancer when declared as a notifiable disease (under the Public Health Act) will help to maximize the sources of data collection, data utilization and enable regular reporting at national level and reporting back to the respective hospitals providing initial data.

There is a wide list of institutions possessing relevant data on cancer incidence and mortality. In addition to hospitals, they include health insurance agencies (government and private), hospitals for indigenous medicine, cancer screening programmes in the public sector and the vital statistics office. All these stakeholders can potentially be providers of data and should be considered while drafting the cancer registry legal framework and any relevant legal act to establish cancer as a notifiable disease. Currently, there is a mixed response rate from major

public hospitals providing data to both the Sri Lanka Cancer Registry and the Colombo Population Based Cancer Registry. It is estimated that <10% of cancer cases seek health care in the private sector and getting data from the private health sector remains a major challenge.

### **Cancer Registry Methodology**

The staff in the existing registries are trained and knowledgeable in disease coding using international norms (ICD-O and ICD-10). There are also standard operating procedures. Senior staff is exposed to relevant international courses. A Data Analysis Software used in Chennai registry has been installed for pilot testing and has been used in generating cancer incidence tables for use in registry reports. There are existing data input tools for both SRCR (customized tool) and Colombo PBCR (CanReg-5). Data are processed to avoid duplication using CanReg-5, LinkPro software and visual scrutiny. Data validity checks are done using IARCcrgTools.

The current methodology could benefit from using the existing Morbidity and Mortality Registry that is operational in all hospitals up to district level. Diseases are coded using ICD-10 and reported as frequencies every month. This registry, however, lacks data on person's name and residence, which will be useful for the cancer registry system.

In addition, the Department of Census and Statistics is a very rich resource of population statistics and of interest for the cancer registry system. The population data are available as hard-copy reports and through the website. A coordination between the Department of Census and Statistics and cancer registries has been established. For the benefit of the national cancer registry system, in addition to already available population statistics, special requests should be made to the Department of Census and Statistics for the following statistics: (i) 5-year age group and sex population for every district from 2012 to 2018 and (ii) population life tables by single year age or abridged life-tables of 5-year age-groups for the period 2012-2018.

### **Cancer Registry Workforce Requirements**

Dedicated workforce is required for multiple tasks related to cancer registry. The deployment of so-called Development Officers (DO) for cancer registry should be implemented in all hospitals at different level of health care, based on their cancer related workload. One Development Officer per 2000 cancer cases will be feasible and justified. This will augment the existing cancer registry activity in the country and assist in getting the required follow up data collection, through repeated scrutiny of medical records and/or telephone inquiries.

### **Cancer Registry Oversight and Coordination**

The registries' oversight and data quality control are carried out by the NCCP office, which requires additional technical support for data conversion, software development and data management. There is a need for additional data entry personnel to complete the backlog of notifications, reports and support active case-finding for the Sri Lanka Cancer Registry and the Colombo PBCR. Continuous trainings should be conducted by the NCCP registry staff on cancer terminology, cancer registration, standard operating procedures and data management.

The NCCP higher officials should keep track of the ongoing developments of information technology infrastructure in the health sector, especially in relation to the establishment of the Personal Health Identification Number. Data linkage outside the cancer registry system should be optimized. Software development for reporting cancer data from remote sources to central registry should be given priority to avoid delays in data management.

A Cancer Registry Technical Committee, a sub-committee of the National Advisory Committee should be established, comprised of stakeholders that will oversee and provide technical guidance to the future developments of the national cancer registry system.

### **Overview of Specific Cancer Registries:**

### 1. Sri Lanka Cancer Registry (SLCR)

The essential elements of a cancer surveillance system are incidence, mortality and survival data. Currently, the entire country is under surveillance through the Sri Lanka Cancer Registry (SLCR). The principal sources of data are cancer hospitals in the public sector at all levels of health care. They report data using the National Cancer Surveillance Form (NCSFs). Pathology laboratories in these major hospitals and the Oral and Maxillofacial (OMF) units in the public sector provide data using the Cancer Registry Form (CRF). Hence, cancer registration for the SLCR is based on passive notifications of new cancer cases reported in a standard format using the designated online portal (web data base NCCPSL) and/or electronic transfer of data. Active case-finding is also done by the registry staff from the National Cancer Control Programme (NCCP) through periodical visits to the provincial hospitals. The SLCR can be described as a quasi-population-based cancer registry (PBCR) generating minimum incidence rates, with very limited data on mortality and no data on survival rates.

### 2. Colombo Population-Based Cancer Registry

There is also a population-based cancer registry (PBCR) covering Colombo district since 2012. It was established to augment the role of Sri Lanka Cancer Registry (SLCR) and to maximize the registration of new cancers by using a combination of active and passive methods. In addition to all SLCR data sources, data on new cancers are received from the department of medical records in both public and private hospitals. The data on new cancers are entered using CanReg-5 software as recommended by the International Agency for Research on Cancer. The data on cancer mortality from hospitals of Colombo district are submitted by registrars of death through the National Cancer Surveillance Form (NCSFs).

The latest report of the Colombo PBCR was in 2012. Data have been collected until 2017, but not processed. Considering this heavy backlog of work, it is impractical to complete data processing for years up to 2017. It is recommended that Colombo PBCR proceeds with data analysis of the most recent years (2018), with completion of mortality data and with trace-back of inquiries for notifications from pathology departments and death certificates lacking data on residence and incidence date. Data from the last 3 years, especially from pathology laboratories combined with other readily available representative data from teaching, provincial and district hospitals can be utilized to estimate the burden of new cancers for Sri Lanka.

#### 3. Hospital-Based Cancer Registry in the Apeksha National Cancer Hospital

Hospital Based Cancer Registry (HBCR) can serve as the nucleus to the Population Based Cancer Registry (PBCR). Out of 9 provinces in Sri Lanka, a HBCR exists only in the Apeksha National Cancer Hospital in Colombo district. It has a medical record department with 23 staff members. Only 2 staff members are assigned with full-time HBCR work: 1 ward clerk for data entry and 1 development officer for disease coding. HBCR staffing is inadequate for 14,314 new cases registered in 2018. There is a heavy backlog of work with the latest report of HBCR produced in 2013. The hospital performance report for 2018 is available without key cancer statistics. Despite the presence of a HBCR, the National Cancer Control Programme (NCCP) office staff has to visit Apeksha National Cancer Hospital every year to collect data by active case-finding to serve both SLCR and Colombo PBCR. A Hospital Information Management System (HIMS) is operational at Apeksha Hospital since 2015. The areas covered are new case registration, in-patient admissions and discharges, radiology, biochemistry and other laboratories. This system is able to generate hospital statistics readily but does not seem to provide data to support the hospital-based cancer registry (HBCR). Since it is impractical to complete backlog work from previous years, it is recommended that the HBCR starts work to bring out the report for 2018. The HBCR at Apeksha Hospital requires additional human resources and office space.

### 4. Karapitiya Teaching Hospital Cancer Information System

The Teaching Hospital (TH) in Karapitiya in Southern Province has a newly appointed development officer for cancer registry related work. The level of documentation and medical records in this hospital are adequate for a cancer registry. The National Cancer Surveillance Form (NCSF) are attached to every medical record. Data are incomplete, as patient information is provided by the nurses/clerks, while the information on the disease is left blank. In addition, the electronic submission of data to the NCCP office is not in place.

#### **Recommendations:**

### **Cancer Registry Legal Framework**

• Short-term (6 to 12 months): Develop a legal framework to enact cancer as a notifiable disease. In addition to hospitals, consider including other intuitions in possession of cancer related data e.g. health insurance agencies, hospitals for indigenous medicine, cancer screening programmes and the vital statistics office. Ensure that the legal framework captures linkages, data exchange and improvements of existing mortality statistics (through the work of the death registrars and the hospital mortality registry) relevant to cancer data;

### **Expanding Cancer Registry Network**

• *Short-term (12 months):* All major cancer treating centres in the public sector should have a hospital-based cancer registry (HBCR) to provide data to existing and forthcoming population-based cancer registries (PBCRs). As a short-term goal (2020), at least 3 to 5 HBCRs should be established in the Teaching Hospitals;

### Workforce Development

- *Short to medium term (within 24 months):* Deploy additional data entry personnel at the National Cancer Control Programme (NCCP) office to complete the backlog of notification forms, reports and support active case finding for the Sri Lanka Cancer Registry and the Colombo PBCR;
- *Medium-term (within 36 months):* Deploy dedicated workforce for cancer registry (Development Officers) in hospitals at different level of care, based on their cancer related workload. One Development Officer per 2000 cancer cases would be feasible and justified. The dynamic of deployment should follow the expansion plan of the hospital-based cancer registry network (*see recommendation under expanding cancer registry network*);
- Ongoing priority: Ensure continuous training of cancer registry staff through i) annual review meetings of cancer registry data (HBCR/PBCR); ii) principles and methods of cancer registry; data management, data analysis and data dissemination trainings; iii) create opportunities to attend regional and international courses in cancer registry organised by the International Agency for Research on Cancer (IARC), International Association of Cancer Registries (IACR) and the regional hub of Global Initiative for Cancer Registry Development (GICR).

### **Cancer Registry Methodology**

• Short-term to medium-term (within 24 months): The NCCP office should keep track of the ongoing initiatives for improving health information technology to facilitate linkages and exchange of data with the existing and future cancer registries. In addition, special requests should be made to the Department of Census and Statistics for the following statistics: (i) 5-year age group and sex population for every district from 2012 to 2018 and (ii) population life tables by single year age or abridged life-tables of 5-year age-groups for the period 2012-2018 to enable further data analysis and reporting through the Sri Lanka Cancer Registry and Colombo Population-Based Cancer Registry;

### **Cancer Registry Oversight and Coordination**

• *Short-term (12 months):* A Cancer Registry Technical Committee, as a sub-committee of the National Advisory Committee (NAC) for cancer control should be established, comprised of stakeholders that will oversee and provide technical guidance to the future developments of the national cancer registry system.

#### **Cancer Registry Reporting**

• *Short-term (within 12 months):* Considering heavy backlog of data analysis, it is recommended to start with data analysis of the most recent years (2018 and onward). Data from the last 3 years, especially from pathology laboratories combined with other readily available representative data from teaching, provincial and district hospitals can be utilized to estimate the burden of new cancers for Sri Lanka. It will be helpful if intermediate reports are prepared every 6 months to monitor the data in-flow and other processes.

#### 2.5. Prevention

The most common cancers in men are the oral cavity, trachea, lung, oesophagus, colorectal and prostate. The most common cancers in women are breast, thyroid, cervical, ovarian and colorectal. A certain number of these cancers can benefit from prevention and early detection activities through tobacco and alcohol control (oral cavity, trachea, lung, oesophagus cancers) HPV vaccination (cervical cancer); and secondary prevention (colorectal and cervical cancers).

#### **Tobacco Control**

Based on the latest STEP survey<sup>14</sup> in 2015, tobacco use is much more prevalent in men than in women. Half of the men population aged 15 and over are current tobacco users under the form of smoking tobacco (29%) and smokeless tobacco (25%). In women, smokeless tobacco is more prevalent than smoking tobacco.



**Table 3.** Prevalence of smoking among those aged 15 years and more



#### Bar Chart 1. Prevalence of current tobacco users in Sri Lanka by gender<sup>15</sup>

<sup>&</sup>lt;sup>14</sup> WHO report on the global tobacco epidemic, 2019 Country profile Sri Lanka; accessed: https://www.who.int/tobacco/surveillance/policy/country\_profile/lka.pdf?ua=1 <sup>15</sup> Ministry of Health of Sri Lanka

Based on the Global Youth Tobacco Survey<sup>16</sup> (2015) aged 13 to 15 years, 3.7% used any type of tobacco product whereas 1.5% were tobacco smokers. Out of the current smokers, 83.9% reported that they have tried to quit smoking during the previous year. 62.2% believed that it was not difficult to quit smoking once someone starts smoking. Out of the never tobacco users, 2.5% indicated that they were susceptible to begin smoking in the future. Boys are more frequent users of tobacco products (smoking and smokeless tobacco), as compared to girls.

Sri-Lanka signed and ratified the Framework Convention on Tobacco Control in 2003.

All MPOWER measures<sup>17</sup> (except Mass Media) are in place: complete policy for health warnings and mostly complete smoke-free policy and advertising bans. Total taxation on the most sold brand represents 66.2% of the smoking tobacco: 47.5% specific excise tax; 10.7% VAT or sale tax; 3.9% other taxes.

Regarding legislation, the National Authority on Tobacco and Alcohol (NATA) Act prohibits:

- Sale of any tobacco or alcohol product to persons under 21 years of age;
- Installation of vending machines for tobacco products;
- Sale of tobacco products without health warnings;
- Tobacco advertisements and sponsorships of any type, including free promotion;
- Smoking in public places;

In addition, there is an initiative to ban single stick sales of cigarettes and prohibit sales of any tobacco product to persons under 21 years of age.

In 2016, Sri Lanka endorsed the Framework Convention on Tobacco Control Protocol to Eliminate Illicit Trade of Tobacco Products, becoming the first country in the WHO South-East Asia Region to do so. This protocol provides tools to prevent illicit trade by securing the supply chain, establishing an international tracking system, as well as measures for law enforcement which enable international cooperation. E-cigarettes are also banned in Sri Lanka.

Besides legislation, health promotion is performed by public health nurses, midwives, volunteers at the primary health care (PHC), through the Healthy Lifestyle Clinics (HLCs), Well Women Clinics (WWCs) or at schools through lectures, posters, testimony of cancer survivors. However, PHC is mostly visited by women. The challenge is to reach out to the most at-risk male population, including "high-risk", simultaneous tobacco and alcohol product users.

Although Sri-Lanka has a comprehensive anti-smoking tobacco programme, in terms of smokeless tobacco, it needs strengthening. In July 2017, Sri Lanka implemented a ban to both imported and locally produced smokeless tobacco products. Locally produced betel quid (betel leaves with areca nut, +/- tobacco leaves, +/- lime) is officially banned since October 2016. However, this product is widely available at a very low cost. Awareness on the harmful effect of betel quid is done individually through the health facility visits or when a person is diagnosed

<sup>&</sup>lt;sup>16</sup>Global Youth Tobacco Survey (GYTS) Sri Lanka 2015, Country Report, accessed: http://www.searo.who.int/tobacco/data/gyts\_sri\_lanka\_2015\_report.pdf?ua=1

<sup>&</sup>lt;sup>17</sup> https://www.who.int/tobacco/surveillance/policy/country\_profile/lka.pdf?ua=1

with oral precancerous lesions. National awareness campaigns against smokeless tobacco habit are challenging to implement because of the negative cultural impact it could have. Betel quid is mostly chewed by the elderly segment of the population (both men and women), from rural settings. Smokeless tobacco flavoured with areca nut is recently getting more popular among the young age group and oral lesions are increasingly observed in this age group.

Smokeless tobacco in the form of betel chewing is a deep-rooted lifestyle habit especially in the villages and estate sector labour communities. No taxes are levied on the entire supply chain. Further, commercial preparations such as *mawa, gutka, panparag, hans, babul and beeda* are becoming popular among the younger generation. In the last quarter of 2018, Sri Lanka in collaboration with the World Health Organization and the Centre for Disease Control conducted the first Global Adult Tobacco Survey, which provided comprehensive data on the use of smokeless tobacco. The preliminary results showed that the reasons for the use of smokeless tobacco are to increase concentration at school or at work, to give courage, and to vanish loneliness. When asked what they will do if smokeless tobacco would not be available anymore, most of them replied they will opt for stronger narcotic substances such as cannabis.

A sub-committee on smokeless tobacco was established under the National Authority on Tobacco and Alcohol (NATA) in 2015. It aims to monitor smokeless tobacco use and formulate preventive policies. Based on the recommendations of NATA, in 2017 the Government issued a regulation that bans the import, marketing and sale of any type of smokeless tobacco product. The enforcement of these regulations faces challenges based on the cultural and historical context of the smokeless tobacco.

The Tobacco Quit Programme has been identified as a priority area for Sri Lanka. A tobacco quit-line has been established in 2010 in Anuradhapura, under the auspice of the Regional Director of Health Services Office. The quit-line will be a key activity in a more comprehensive service for tobacco cessation and will include a network of trained counsellors and mental health specialists. Preparations, including training of health personnel are underway to provide support for smoking cessation through the Healthy Lifestyle Centres (HLSCs).

Smoking cessation clinics are available. Nicotine Replacement Therapy (NRT) is not recommended as a policy. Few practitioners prescribed it. NRT, Bupropion, Varenic line are not legally sold in Sri-Lanka, and NRT is not on the essential drugs list<sup>18</sup>. Smoking cessation support requires expansion, as it is not available at the hospital and primary health care level. The cost of treatment of tobacco dependence is fully covered by the health insurance for visits at the office of a health professional and partially covered in the community services.<sup>19</sup>

<sup>&</sup>lt;sup>18</sup> WHO report on global tobacco epidemic 2019

<sup>&</sup>lt;sup>19</sup> WHO report on the global tobacco epidemic, 2019, Country profile Sri Lanka; accessed: https://www.who.int/tobacco/surveillance/policy/country\_profile/lka.pdf?ua=1

### **Alcohol Control**

Alcohol control is under the responsibility of the National Authority on Tobacco and Alcohol (NATA). In the latest STEP Survey (2015), 34.8% of men and 0.5% of women aged 18 to 69 consumed alcohol. The total annual alcohol consumption per capita ( $\geq$  15 years of age) is 4.3 litres of pure alcohol compared to 6.4 litres globally.

Table 1.4: Tobacco and alcohol use in Sri Lankan population in the year 2015 (selected age groups) <sup>19</sup>					
		Age group	Male	Female	
Smoking (%)	Never smoked	30-44yrs	52.1	99.8	
		60-69yrs	36.7	99.8	
	Daily smoking	30-44yrs	22.6	0.0	
		60-69yrs	22.0	0.0	
Smokeless tobacco (%)	Never used	30-44yrs	65.7	95.6	
		60-69yrs	55.5	86.5	
	Used daily	30-44yrs	21.3	2.4	
		60-69yrs	34.6	10.7	
Alcohol use (%)	Never used	30-44yrs	34.5	96.6	
		60-69yrs	30.9	94.8	
	Current user (within past 30 days)	30-44yrs	42.3	0.3	
		60-69yrs	33.6	1.0	

**Table 4.** Tobacco and alcohol use by age group and gender

Another survey conducted in 2017, reported annual consumption of 2.4 litres of pure alcohol per capita (( $\geq 15$  years of age). According to this survey, hard liquor (arrack) consumption accounted for around 70% of the per-capita consumption. It is estimated that consumption of illicit alcohol is less than 8% of the overall per-capita consumption.<sup>20</sup>

Very often, alcohol users are the same population as tobacco users, coming from low socioeconomic status and facing family problems. Mostly civil society organizations such as ADIC is reaching out to the school-aged and adult population to increase awareness through social media and health promotion at schools.

Sri Lanka is implementing several cost-effective interventions:

- Taxation and pricing policies;
- Drink-driving policies and measures. Sri Lanka has set the maximum legal blood alcohol concentration when driving a vehicle at 0.08%. Worldwide, the maximum permissible blood alcohol concentration for drivers is commonly between 0.05–0.07% (61 countries) or 0.08–0.15% (46 countries)<sup>21</sup>;
- Availability of alcohol;
- Marketing of alcoholic beverages.

<sup>&</sup>lt;sup>20</sup> Leifman H (2018) Trends and patterns of alcohol consumption in Sri Lanka 1981-2017- analyses of sales and survey data. Alcohol and Drug Information Centre (ADIC), National Authority on Tobacco and Alcohol (NATA) and The Swedish Council for Information on Alcohol and Other Drugs (CAN). Sri Lanka 2018. Information on Alcohol and Other Drugs (CAN). Sri Lanka 2018.

<sup>&</sup>lt;sup>21</sup> Global status report on alcohol and health 2014. Geneva: World Health Organization; 2014. (http://www.who.int/substance\_abuse/publications/global\_alcohol\_report/msb\_gsr\_2014\_1.pdf?ua=

The alcohol control public health interventions and related legislation faces several challenges in implementation. For example, there is no low-price limit for selling alcohol and alcohol consumption is adverted through the movie industry. In addition, in few occasions the Ministry of Finance decreased taxes on beer and cigarettes (Bristol and Navigate). All these violations of the NATA Act are documented and reported.

### **Physical Activity and Diet**

According to the STEP Survey in 2015, 22.5% of men and 38.4% of women are physically inactive. Overweight is reported in 23% of the adult population aged 18-69 years and 6% are obese. In South-Asian population, abdominal fat should be measured instead of the body mass index. No data on abdominal fat (determinant of NCDs) was provided.

Through collaboration of several ministries (Health, Sports, Education, Higher Education, Social Services, Public Administration, Child Care and Women Development, Youth Affairs and Urban Development), several public health programmes are in place<sup>22</sup>:

- Community-based programmes:
  - Recreational parks, cycling tracks, secured walkways with urban development
  - Effective workplace concept: fitness centres in private and state institutions; regular health check-ups of employers
- Out-of-school youth programmes with vocational training centres that include health promotion on substance abuse, non-communicable diseases, reproductive health, diet and physical activity;
- School-based programmes coordinated by the Family Health Bureau. These include counselling on life skills development and nutrition policy in school canteens.

Less than 30% of the population have 5+ servings of fruit and vegetables daily. This is explained by the fact that vegetables and fruits (in particular) are costly compared to 'junk' food. There is no organized system for preservation of locally produced fruit and vegetables.

Sri-Lanka implemented a tax on sugary drinks since 2018. The rate is 30 cents per gram of sugar in sweetened beverages. There is a plan to set up upper-limit of sugar in sweetened drinks.

### Immunization

Sri-Lanka has 2% prevalence of chronic hepatitis B infection (prevalence of hepatitis B surface antigen) in the general population.<sup>23</sup> Sri Lanka has a policy of immunizing healthcare workers at risk of HBV.<sup>24</sup> Sri Lanka has included HBV immunization in the Expanded Programme of Immunization (EPI) since 2003, with 3 doses at 2, 4, 6 months. There is a high coverage of HBV vaccination with 99%. There is no birth dose and no planto introduce a birth-dose vaccine

<sup>&</sup>lt;sup>22</sup> NCD book p 100-105

<sup>&</sup>lt;sup>23</sup> WHO. Global and Country Estimates of immunization coverage and chronic HBV infection, 2015. http://whohbsagdashboard.com/#global-strategies

<sup>&</sup>lt;sup>24</sup> Noordeen F et al. A review of hepatitis B virus infection in Sri Lanka. Sri Lankan Journal of Infectious Diseases 2015 Vol.5 (2):42-50
due to low prevalence (<1%) of disease in those aged less than 5 years and high vaccine coverage over 95% in those over 15 years.

HPV vaccination started in October 2017, using 2 doses of HPV quadrivalent vaccine. This is a compulsory school-based programme targeting 10-11 years old girls. There is also a programme covering out-of-school girls through community-based clinics. There is a specific registry developed and monitoring system that shows 93% coverage of the 1<sup>st</sup> dose and 90% of the 2<sup>nd</sup> dose. Adverse effects are closely monitored following any immunization through home visits by midwives in the community, 1 month after any vaccination.

The immunization programme is fully covered by the Ministry of Health with a budget for several years. No issues with the vaccine procurement process have been reported.

**Recommendations** (responsible stakeholders/institutions are put in brackets):

# Short-term (6 to 12 months)

- Strengthen tobacco control enforcement measures (targeting betel quid) by increasing the role of medical officers of health and public health inspectors;
- The revenues from excised taxes from tobacco and alcohol products should be used for health preventive activities (Ministry of Finance through NATA);
- Work with sociologists, behavioural scientists, and national/international organisations to modify the behaviour of vulnerable and at-risk population (Health Promotion Bureau with the collaboration of NCD, Mental Health Division, NCCP, WHO);
- Strengthen tobacco quit-line programme through increase in the number of counsellors (NATA);
- Continue community and school-based programmes to increase physical activity (NCD unit with collaboration other stakeholders);
- Consider initiating data collection of abdominal fat (waist-to-hip ratio) instead of weight and height (used to measure BMI) at the WWCs and HLCs as more appropriate Sri Lanka;
- Sustain the high coverage level of vaccination (Epidemiology unit).

# Medium-term (12 to 36 months)

- Modify the existing legislation of the NATA Act to strengthen control over tobaccomixture products (NATA);
- Introduce regulations on areca nut and other carcinogenic products (NATA and other Regulatory Authority such as occupational health, environmental health, and food safety);
- Increase taxes on all types of tobacco products. Unaffordability of alcohol and tobacco products is the public health measure that has proven effective (NATA);
- Strongly consider introducing excise taxes on raw tobacco;
- Continue to increase awareness on the harmful effects of alcohol and tobacco in children and adolescents through several educational programmes (School-Based Health Programme of Family Health Bureau with collaboration of Ministry of Education)

- Consider using Nicotine Replacement Therapy (NRT) as appropriate measure for tobacco cessation, after consultation with different stakeholders (psychiatrists, etc.);
- Strengthen legislation on added sugar in drinks, food, and labelling of all food companies (including local distribution) (Occupational health, environmental health and food safety);
- Make fruits affordable to the population and increase health promotion on fruit and vegetables consumption (NCD unit and Nutrition unit).

### Long-term (36 months and above)

• Measure regularly the prevalence of risk factors and health promotion activities, to monitor the effects on the health status of the population (example, number of persons using the quit-line) (divisions in charge of a specific programme)

### 2.6. Early Detection

Most of the cancer patients are diagnosed at a late stage (III and IV): 33% for breast cancer, 52% for cervical cancer and 72% for oral cancer. These findings prompt the importance of early detection programmes in the context of Sri Lanka.

The country has implemented two approaches of cancer early detection - screening of asymptomatic individuals and early diagnosis of symptomatic persons. Early diagnosis is the main approach. Both opportunistic and organised screening are done. Budget for early detection is decided annually, although it should be for a longer period (5 to 10 years).

Early detection is provided in several health facilities in the public sector. The Well Women Clinics (WWCs, total of 942 clinics) programme targets women aged 35 and 45 for breast, cervical and thyroid cancer screening. The target population is identified through the population register and approached by public health midwives through home visits. The Healthy Lifestyle Centres (HLCs, total of 900 clinics) are primary health facilities where prevention and early detection of the main non-communicable diseases (in men and women), are provided (breast and oral cancer screening). Dental clinics (approximately 800 clinics) are dedicated to oral diseases. An early detection centre is available in Colombo with public-private partnership and provides opportunistic screening for breast, cervical and oral cancers.

The objective of cancer early detection programme is to reduce the mortality and to reduce the incidence of cancer that can be detected at a precancerous stage, like cervical or oral cancer. In terms of cancer early detection, the programme in Sri Lanka is focusing on oral, cervical, breast and thyroid cancers. Below, we will review each programme. In absence of most recent data, we cannot conclude the impact of early detection programme on cancer mortality/incidence.

#### **Oral Cancer and Precancerous Lesions**

The oral cancer screening is the oldest early detection programme in place (since the 1990's but reinforced less than a decade ago). This is an opportunistic programme well-documented with detailed guidelines. Oral cancer is the most common cancer in men. It is usually diagnosed in the low socio-economic status (farmers, mine workers, bus drivers, fishermen, plantation

workers). Risk factors are well-known, and it is mainly due to habits of tobacco and/or alcohol use. Awareness on the harmful effect of tobacco and alcohol is given to the general public at through the Health Lifestyle Centres (HLCs) available at primary health care level. Individuals are asked about their habits (e.g. frequency of chewing betel quid daily; habits of alcohol and smoking tobacco; use of areca nut). If they are classified as high risk population according to their habits, they are referred to the nearest dental clinic (approximately 800 clinics nationwide) where they receive visual inspection of the oral cavity. If a precancerous lesion is observed, the person is referred to the Oral and Maxillofacial Surgery (OMF Surgery) unit for a biopsy to be done by an OMF surgeon. If a cancer is not diagnosed, the patient may be followed up by the referring dental surgeon. If an oral cancer or oral epithelial dysplasia is diagnosed, surgical management will be carried out by the OMF surgeon.

Often, because the treatment of oral precancerous lesions such as submucosis fibrosis is mutilating, most of the patients prefer using traditional medicine to avoid surgery, leading to late referral and advanced stage at diagnosis. Another challen ge is that the high-risk population is difficult to convince to stop their habits for cultural reasons. Additionally, men are difficult to reach because they do not visit the HLCs, the patients being mainly females (about 75%).

### **Cervical Cancer**

Sri Lanka set the objective to reduce cervical cancer burden by 60%. In the national programme, cervical cancer is screened by cytology, twice in the lifetime. Women can be screened at one of the 942 Well Women Clinics (WWCs). The national programme started in 1998. Initially, screening was opportunistic and since 2007, it is an organised programme, with a defined target group i.e. women aged 35. In 2018, women aged 45 were also added to the target age for cervical cancer screening. If a woman is screened at age 35, she will be recalled at age 45. Outside this target age groups (35 and 45), women can be screened from age 35 to 60, in an opportunistic fashion, without invitation from the public health midwives. The primary screening test is the conventional Pap smear. Women are contacted either in person or by phone and requested to come to the clinic on a given date and time. The recruitment objectives are given to the WWCs and are monitored. Opportunistic screening is also carried out in some gynaecology clinics (public and private sector), or by civil society organizations (e.g. Cancer Early Detection Centre in Colombo run by the Rotary Club) but not as a routine activity.<sup>25</sup> The cytology (Pap smear) providers at the WWCs are medical officer and public health nurse. They were trained once. If a cytology is positive (defined as ASCUS and over), the woman is advised to have a colposcopy. There are 11 colposcopy units only in the public sector. Cytology reports take 1 to 2 months on average, but sometimes much longer.

About 3 years ago, a demonstration project on cervical cancer screening using VIA screening method was implemented by a civil society organization in the North province of the country. The availability of trained cyto-screeners was a key element to decide to run a cytology-based cervical cancer screening instead of a VIA-based screening or the "screen-and-treat" approach. However, Sri-Lanka is currently lacking cyto-screeners. On the other hand, in 2018, a pilot

<sup>&</sup>lt;sup>25</sup> Annual Health reports, Family Health bureau, Ministry of Health

project<sup>26</sup> using HPV-DNA testing as a primary screening test was conducted in Kalutara district using the Cobas 4800 HPV test system (Roche, Basel, Switzerland), in the same target age groups as Pap smear (35 and 45). The pilot project was very well designed. The results are under completion but there are concerns on the scaling up because of affordability and sustainability issues (i.e. cost of consumables). Linked to this demonstration project, in 2020, UNFPA will perform a cost-benefit analysis of HPV-DNA testing as a primary screening test.

In 2018, the participation to screening at the WWCs among invited women aged 35 was 61.2%, and 56.1% of women were actually screened with cytology (the difference of 5.1% is explained with no possibility to take smears if the woman has menstruation). The cytology screening participation was only 15% in women aged 45 (low participation rate explained by the recent (2018) introduction of the programme in the respective age group).<sup>27</sup>According to another source from earlier years, the participation rate to the cervical cancer screening is lower. Based on the STEP Survey in 2015, 25% of women aged 30 to 49 years had been screened for cervical cancer in Sri-Lanka.<sup>28</sup>

The imPACT expert team visited a primary health facility in Kurunegala district. A cervical cancer screening activity is organised once per month, in the morning hours. In the district, the total female population aged 18 and over is 3000 women. The 35 years old women represent 1% of the population (30 women) and those 45 years old 0.8% (24 women). A total of 54 women should be screened per midwife annually. Since there are 4 midwives, 220 women are expected to be screened per year. In 2018, 261 Pap smears were taken through the screening programme. If positive, the woman needs to take an appointment for colposcopy. If cervicitis is diagnosed, a smear is not taken, the woman is requested to seek for treatment before having a smear at the Well Women Clinics (WWCs).

The Ministry of Health (Family Health Bureau) is equipped with an electronic monitoring system that reports the participation rate for the whole country in real time, with grouped data. In each Regional Director of Health Services area, the medical officer of health has an electronic data base, with dedicated staff to enter data only from the public WWCs programme. Additional activity from other facilities such as private sector or NGOs is not included. The performance measures are limited to the participation rate. There is no information on the positivity rate of cytology (defined in Sri Lanka by the number of ASCUS and over among the total women screened), the colposcopy rate among those screened positive, the cervical cancer detection rate (number of cervical cancer cases among the total of women screened). The percentage of inadequate smears is less than 5%, which is a very good performance.

There is no proper referral and referral-back system. At the WWC level, there is no information if the woman had colposcopy, biopsy and cancer management. The imPACT expert team was informed about a high rate of loss-to-follow up, however, this cannot be captured in the current monitoring system. There are no performance indicators available, except participation rate in

<sup>&</sup>lt;sup>26</sup> Ministry of Health, Family Health Bureau, Well Women Programme, National Strategic Plan, 2019

<sup>&</sup>lt;sup>27</sup> eRHMIS, Family Health Bureau

<sup>&</sup>lt;sup>28</sup> Non-Communicable Diseases Risk Factors: STEPS Survey Sri Lanka 2015; accessed: https://www.who.int/ncds/surveillance/steps/STEPS-2015-Fact-Sheet-Sri-Lanka.pdf

place (target of 80% participation to screening by 2023), nor national standards. For instance, based on previous studies, at the age of 35, one expects a positivity rate of cytology less than 3% (defined as ASCUS + lesions) and 4% in women aged 45 years. All the expected indicators are currently missing.

# **Breast Cancer**

The early detection programme started in 1996. Women can be screened for breast cancer at the Well Women Clinics (WWCs), the Healthy Lifestyle Centres (HLCs), civil society organizations (CSOs) and the private sector. In the public sector, women receive information and education on self-breast examination. The primary screening test is clinical-breast examination (CBE) performed by the medical officer or the public health nurse. At the WWCs, screening is organised among the same target population as for cervical cancer screening (aged 35 and 45). At the HLCs, CBE screening is opportunistic, starting at 35 years old, performed annually. If abnormality is detected, the woman is referred for mammography, ultrasound, fine needle aspiration cytology (FNAC) and referral for further investigations and treatment). The imPACT Review team was informed about a lack of mammographs (21 machines in the public sector), used for diagnostic mammography and not for screening purposes. There is an issue of male radiographers preventing women to seek mammography, however, with the presence of a chaperone, this could be acceptable.

Similar to the cervical cancer screening, the monitoring system at the Medical Officer of Health measure limited performances of breast cancer screening at the WWCs such as participation rate, but no referral data and no cancer detection rate. For instance, in Kurunegala province, in 2018, 21333 women aged 35 received a CBE (101% of coverage objective), and 297 had a CBE positive (1.4% positivity rate). Similar for cervical cancer screening, there are no performance indicators, nor national standards. For instance, based on previous studies, we expect a positivity rate of CBE in women aged 45 of 5%, and among those CBE positive receiving mammography, 10% abnormal mammography (example, among 1000 women aged 45 screened by CBE, 50 will be CBE positive and 5 will have an abnormal mammography).

# **Thyroid Cancer**

Thyroid cancer is screened by medical examination in women, at age 35 and 45 at the WWCs. Thyroid cancer screening has been implemented since 2018 because thyroid cancer is the 3<sup>rd</sup> most common cancer in women (according to GLOBOCAN data) and because its incidence is increasing. Data from the Ministry of Health also show that the mortality from thyroid cancer is very low and stable over time. Based on international evidence, screening programme for thyroid cancer is not recommended because the mortality will not be reduced.<sup>29</sup> Early diagnosis of symptomatic women should be the preferred option.

<sup>&</sup>lt;sup>29</sup> https://www.cancer.gov/types/thyroid/hp/thryoid-screening-pdq

#### **Other Cancers**

**Prostate cancer** screening is not promoted by the Ministry of Health (MoHNIM) and this follows the WHO recommendations.<sup>30</sup> However, in the private sector, PSA testing method is proposed to men from 50 years of age.

**Colorectal cancer** screening is currently not promoted by the Ministry of Health (MoHNIM) because of the limited diagnosis capacity in the public health sector (e.g. lack of endoscopy clinics; endoscopists etc.).

In summary, Sri Lanka already implemented numerous elements of early detection programme, but several challenges exist: i) inappropriate target age population for breast cancer screening (weakening the programme); ii) limited number of diagnosis facilities; iii) low workforce density and uneven distribution; iv) weak coordination of early detection and treatment services; and v) absence of a monitoring system. With exception of WWCs, there is a lack of comprehensive surveillance system. Key performance indicators for an early detection programme are not captured, such as follow up and treatment outcomes of screen positive.

There is a lack of referral system and loss to follow-up which cannot be quantified (estimated by the counterparts > 50%). Once a case is diagnosed positive, there is no possibility to trace and verify further assessments, referral and final diagnosis. The number of diagnosis facilities in the public sector (colposcopy, mammography, etc.) is not sufficient. There is a shortage of staff (cyto-screeners, female radiographers, pathologists) and availability of national training programme on early detection. National guidelines on cancer screening are documented, but there are no performance indicators (except participation rate) and no national standards on the performance of an early detection programme. A regular monitoring of the early detection programme would allow quality assurance.

# **Recommendations:**

# Short-term (6 to 12 months)

- Strengthen the referral-up and referral-back system of screened positive cases or early diagnosed cases (*NCCP through the district and provincial director of health services to provide guidance e.g. specific forms to doctors at secondary and tertiary levels*). As part of these activities, consider decreasing the number of visits prior final diagnosis for oral, cervical and breast cancer and link the screening health care to diagnosis health care level;
- Update screening guidelines with national standards for screening programme performance indicators and monitor these indicators;
- Analyse the results of the pilot study on cervical cancer screening by HPV-DNA testing in terms of affordability and sustainability before scaling up the programme. The cost-benefit analysis is also needed (anticipated collaboration with UNFPA in 2020);

 $<sup>^{30}\</sup> WHO.\ http://www.euro.who.int/en/health-topics/noncommunicable-diseases/cancer/policy/screening-and-early-detection$ 

- Consider doing CBE in women aged 45 and over and stop doing CBE in women aged 35, because it will detect mostly benign lesions that will need to be referred for mammography, increase the financial burden on the health system and increase anxiety among women;
- Stop screening systematically 35- and 45-year old women at the WWCs for thyroid cancer. Examine the determinants of thyroid cancers to explain the continuous increased incidence that seems not related to screening activity, before implementing screening programme through the WWCs. Screening for thyroid cancer will not decrease mortality from thyroid cancer (aim of screening), moreover, it will increase anxiety in screened positive women and increase the burden on the health system and health service;
- Continue not screening asymptomatic men for prostate cancer using PSA test, as this is not a recommended screening practice;
- It is not recommended to screen for colorectal cancer because of the shortage of endoscopy facilities and adequate human resources.

# Medium-term (12 to 36 months)

- Strengthen the oral cancer screening programme by improving the coverage of the highrisk population, by improving the referral adherence to biopsy and by improving treatment coverage of cancerous lesions. Develop a similar online monitoring system (as in the case of cervix, breast and thyroid cancers) for oral cancer screening in men and women;
- Based on the developed national standards for performance indicators of an early detection programme (*see third short-term recommendation*), include additional performance indicators in the online monitoring system e.g. result of the diagnosis (mammography, colposcopy) among the screened positive women; result of the biopsy among the screened positive women; result of the biopsy among the screened positive women; result of the biopsy among the screened among those histology-confirmed; number and stage of cancers detected among those screened (as grouped data);
- Use master trainers to train annually or biannually the primary health care staff on cancer signs and symptoms; Pap smear examination; CBE if necessary;
- Increase the number of staff at the primary health care level (public health nursing officer, medical officer) and increase the diagnosis capacity with adequate staffing and equipment (cyto-screeners, colposcopy, mammography);
- Ensure long-term (5-10 years) budget planning for screening/early diagnosis programmes.

# Long-term (36 months and above)

• Consider using the unique national ID/personal ID in all databases (screening, laboratory, hospital) for easy linkage and follow up (*ID number will be implemented in few years to strengthen health system in collaboration with the World Bank*).

#### 2.7. Diagnosis

#### 2.7.1 Pathology and Laboratory Services

There are total of 23,530 new diagnoses of cancer in Sri Lanka and a total of 87 consultant histopathologists (who offer services for not just cancer but all diseases). This number needs systematic augmentation over the next 5-10 years. There are 57 consultant histopathologists in the Ministry of Health, 21 in the Ministry of Higher Education, 2 in the Ministry of Defence, 2 are associated with a semi-government hospital, and 5 in the private sector. A majority of cancer diagnoses, approximately 80% are made in the public sector. The distribution of histopathologists in the provinces varies. For example, there are 24 consultant histopathologists in the Western province and only 1 in the North Central province. Six histopathologists are pending board certification this year. Currently there are 80 trainees, but this is not adequate to cover the needs. In order to overcome pathology shortages, a proposal has been submitted to the MoHNIM to allocate pathologists as follows: 1 pathologist for Base Hospitals (BH) grade A where samples are more than 1500 per year; 1 pathologist for District General Hospitals (DGH); 2 pathologists for Provincial General Hospitals (PGH); at least 2 pathologists for Teaching Hospitals (TH) where there are more than 5000 samples per year; and 3 pathologists for TH with more than 7500 samples per year. At Apeksha National Cancer Hospital, 4 pathologists are needed due to additional workload from referrals and planned expansion into molecular and genetic testing.

Pathologists after completing their overseas or local training may be assigned to hospitals without adequate pathology laboratory facilities (sometimes not even a microscope). Much time is spent trying to establish a laboratory and there is no opportunity to use (and practice) recently learned skills while the laboratory is being established. Young pathologists may be better served by working in a teaching hospital for a period of 1 year following their return to Sri Lanka after completing their overseas training before being assigned to remote locations without pathology facilities. During this 1 year, young pathologist can be assigned to work in the laboratory to which he/she will be assigned in order to develop the needed laboratory facilities/services.

In addition, there are 70 consultant haematologists: 50 consultant haematologists in the Ministry of Health, 12 in the Ministry of Higher Education, 2 in the Ministry of Defence, 1 in a semi-government hospital, and 5 in the private sector. The distribution of haematologists in the provinces varies. Haematologists provide both laboratory and clinical services. Currently, there are 80 trainees in haematology, which should cover needs. Autologous bone marrow transplant is only available at the Apeksha Hospital. Allogeneic transplant services are not available in the public sector at present, although 2 centres are planning to start and the 3<sup>rd</sup> transplant centre is planned in Kandy. Both autologous and allogenic bone marrow transplant services are available in the private sector. Only 1 hospital under the MoHNIM has a dedicated haematology ward. Only 6 centres under the MoHNIM and 1 at a semi-government hospital have flow-cytometry facilities, and most are in the Western province. MRD (minimal residual disease) detection by flow-cytometry is not performed in Sri Lanka, but it is planned to start at the Apeksha Hospital.

There are 25 consultant chemical pathologists, which include 18 in the MoHNIM, 5 in the Ministry of Higher Education, 1 in the Ministry of Defence and 1 in the private sector. Currently, there are 40 trainees in chemical pathology.

There is a wide variation in the number and availability of laboratory and pathology services in the country. The availability of essential pathology diagnostic services in relation to the level of health service requirements in each region is mismatched. For example, the teaching hospital of the North Central province does not have a board-certified histopathologist, and the workload would justify at least 2 board certified histopathologists. The Apeksha Hospital is a main referral centre for diagnostic review as well as immunohistochemistry (IHC) testing. Although oncology IHC services are available at approximately 8 centres, with 4 in the western province, 1 each in Central, Northern, Northcentral and Southern province. Three additional hospitals are planning to implement IHC services: 1 at the North Colombo Teaching Hospital in the Western province; 1 in Sabaragamuwa; and 1 in Eastern province. However, IHC services are needed in Uva province, North Western province (either in Teaching Hospitals or Provincial General Hospitals). In the Southern province, although IHC testing is available, there is no designated laboratory space or dedicated personnel for this service. On long-term basis, in District General Hospitals which are served by consultant oncologists, at least basic IHC markers should be available. The number of IHC markers available should be expanded, including, but not limited to the following antibodies: HBME1, TLE, CDX2, P16, P18, MSI, CD4, EBER, SOX 11, Beta catenin, Uropolakin, AMACR, GCDFP, 34 B12, PAX8, PAX2, CAIX, D240. Continuous supply of antibodies is often disrupted, and this has to be addressed. In addition, IHC markers required for haematological malignancies including, but not limited to: CD33, CD13, CD4, kappa, lambda, CD41, CD61, SOX11, Annexin II, CD103, CD123, CD25 should be available throughout the country.

Genetic/molecular testing in malignancies is planned, but currently is not available in the MoHNIM public sector. They are however, performed in some Universities such as the Faculties of Medicine, Colombo and Ragama. Plans are underway to start a genomic testing at Apeksha National Cancer Hospital (ANCH) and National Hospital of Sri Lanka (NHSL). Required genetic tests are sometimes outsourced to India, which is costly to the patient. Genetic testing is available in the private sector, but it is also very costly.

Tissue-based pathology services are even more limited. Many pathology specimens are sent to tertiary care facilities for interpretation. This leads to these facilities being overworked and cause reporting delays to the referring medical services. There is inadequate infrastructure for transporting tissue blocks for biomarker testing to referring laboratories and in obtaining results from these laboratories. Much of this work falls to the pathologist, which creates undue burden. The delay in getting results to patients and their treating physicians can be weeks to months. The system for result reporting is manual, with hand-written results from the pathologists being transcribed and a hard copy produced. Standardized report templates are not used. There is no electronic system for result reporting in histopathology, haematology, and chemical pathology.

None of the public sector laboratories are accredited by the Sri Lanka Accreditation Board (including histopathology, chemical pathology, and haematology). Each facility follows its

own guidelines on specimen preparation and transport. There is no external quality control on immuno-histochemical testing. Some private hospitals are accredited for chemical pathology, histopathology and haematology. The quality exists for accreditation of the chemical pathology at the Apeksha National Cancer Hospital. Quality assurance practices are not established for histopathology. There are limited quality assurance practices in haematology.

Biological safety and environmental safety in laboratories and pathology services are lacking. Even basic safety measures such as eye wash stations are not available. Some laboratories do not have a separate grossing station. Dedicated specimen storage is not available, and specimens are stored in open shelving in some laboratories.

Written standard operating procedures (SOPs) are lacking. There are no national guidelines for reporting on results. Almost all the hospitals deliver the histopathology reports manually to the patient or to the clinician. There is no laboratory networking system.

A continuing medical education programme does not exist. Funding for attendance at academic meetings is not available. There is attrition in talented pathologists ("Brain Drain").

# **Recommendations:**

### Short term (6 to 12 months):

- Establish infrastructure and mechanisms for timely testing and reporting of results to patient's treating physician. This may involve implementing an electronic medical record system for pathology and standardization of pathology reports. The College of American Pathology, the Royal College of Pathologists, the National Cancer Grid of India and several other organizations have template (<u>https://www.cap.org/protocols-and-guidelines/cancer-reporting-tools/cancer-protocol-templates</u>) reports for their own use that may be modified for use in Sri Lanka;
- Establish SOPs for laboratory safety and waste disposal. Appoint safety officers for each laboratory. This is a basic requirement for any laboratory services;
- Develop written standard operating procedures (SOP) for laboratory evaluations and quality assurance;
- Develop a Clinical Advisory committee (*could be a technical sub-committee under the auspices of the National Advisory Committee on Cancer Control*) that includes consultant haematologists, histopathologists, and chemical pathologists nominated by the respective colleges, headed by the Deputy Director General Laboratory Services and in addition Director Laboratory Service, Provincial Directors of Health Services when relevant. This committee can assist in allocation of human resources, supplies and necessary funding;

# Medium-term (12 to 24 months):

• Increase capacity for basic pathology services in the provinces. This would involve planning for and establishing pathology centres of excellence on a regional basis that can perform central laboratory testing for serum tumour markers, IHC, flow cytometry. This requires an adequate infrastructure and network to ensure timely testing and reporting of

results. Recently trained pathologist can work in these centres of excellence for 1 year following return to Sri Lanka after completion of foreign training to practice their skills before being assigned to remote locations to establish regional laboratories.

- Pursue accreditation of government laboratories to assure quality;
- Develop information sharing/networking system of laboratories within hospitals and then at national level;
- Develop testing for genetic markers including detection of minimal residual disease (MRD) at Apeksha Hospital and National Hospital of Sri Lanka;
- Develop dedicated haematology wards in teaching hospitals and day treatment units in District General Hospitals and above.

### Long-term (36 months and above):

• Develop continuing medical education programme for consultants; online and blended learning modules may be considered. Provide financial support for attending academic conferences and other academic activities.

### 2.7.2 Diagnosis Imaging and Nuclear Medicine (including treatment)

There is a general shortage of radiologists across the country and lack of female radiographers. These are main obstacles for planning and effective implementation of national diagnostic imaging services and major challenge to establish a breast cancer screening programme. There is a general shortage of nuclear medicine physicians, and only 3 nuclear medicine physicians are certified and available in the country. There is a well-established postgraduate degree programme in radiology, but there is no postgraduate degree programme in nuclear medicine. There is no recognition of nuclear medicine as a separate medical speciality.

#### **Nuclear Medicine**

Nuclear medicine (NM) facilities that operate under the auspices of the Ministry of Health (MoHNIM) are concentrated into five provinces.

- Western Province (Colombo) with 3 public hospitals: i) Lady Ridgway Children Hospital exclusive for paediatric NM imaging; ii) National Hospital Sri Lanka only for NM imaging; iii) National Cancer Hospital (Apeksha) at Maharagama, which has NM imaging PET/CT and gamma camera imaging, and NM treatment radioiodine (RAI) therapy.
- Southern Province (Galle) Karapitiya General Hospital provides gamma camera imaging and radioiodine (RAI) therapy.
- **Central Province (Kandy)** NMU Faculty of Medicine, Peradeniya provides radioimmuno-assay (RIA), SPECT gamma camera imaging, bone densitometry and radioiodine (RAI) therapy unit, with post therapy whole body scan facilities.
- North-Western Province (Kurengala) and Uva Province (Badulla) Oncology units at the Teaching Hospital Kurunegala and the Teaching Hospital Badulla have RAI therapy facility, for outpatient and inpatient care, respectively. There are no post therapy imaging facilities in both hospitals.

There are four private NM facilities in the country. All concentrated in Colombo city: i) the Lanka Hospital Pvt/Ltd for gamma imaging only; ii) Asiri Surgical Pvt. Hospital provides PET/CT and gamma imaging facilities; iii) Ceylinco Hospitals Pvt. Ltd and iv) Oasis PVT Hospitals with in-patient facilities for radioiodine therapy.

There are seven NM imaging departments, which include seven SPECT gamma cameras together with three PET/CT scanners (public: Apeksha National Cancer Hospital; National Sri Lanka Hospital (Neurology unit) and the third one is private, Asiri Surgical Pvt. Hospital). However, only two PET/CT scanners are operational (at Asiri and Apeksha hospitals), running with great difficulties, importing FDGs from India at high cost. 40-60 PET/CT scans are done per month in each of the facility. There are no SPECT/CT machines available in Sri Lanka.

Once every two weeks, 99Mo generators are imported and distributed to each facility by the Ministry of Health. Out of these, 99mTc isotopes are produced and then 99mTc based radiopharmaceuticals. These are used to perform bone scan, renal scan, thyroid scan, cardiac scan and parathyroid scan. They are prepared routinely at each facility by trained nuclear medicine technologists/radiographers, as no radio-pharmacists are available in the country. No PET cyclotron is available in-spite of having three PET/CT scanners. At the same time, two additional PET/CT scanners in Kandy and Jaffna hospitals are planned.

Radioactive-iodine 131 (RAI) is the only therapeutic radionuclide used in Sri Lanka for both benign and malignant thyroid diseases. There are nine radioiodine therapy units available in the country, including public and private sector. In-patient therapy facilities for high activity therapy are available in six hospitals (4 public and 2 private). Other hospitals use low activity treatment 1110 MBq (30 mCi), as outpatient service. Please see details in the Table 5 below:

Government facilities	
Apeksha Hospital	high dose, in-patient; imaging facilities available
Karapitiya Teaching Hospital, Galle	high dose, in-patient; imaging facilities available
NMU University of Peradeniya	low dose, out-patient; imaging facilities available
Kurumegala teaching hospital	high dose, in-patient; no imaging facilities
Badulla General Hospital	high dose, in-patient; no imaging facilities
Kandy – Oncology Unit	low dose, out-patient; no imaging facilities
Private hospitals (all in Colombo)	
Celynco cancer hospital	high dose, in-patient; no imaging facilities
OASIS	high dose, in-patient; no imaging facilities
Asiri surgical PVT Hospital	low dose, out-patient; imaging facilities available

 Table 5. Overview of I131 therapy in Sri Lanka

# **Diagnostic Imaging**

For diagnostic imaging, most of the departments are equipped with mammography, computer tomography (CT) scan, magnetic resonance imaging (MRI), ultrasound imaging (US), X-rays machines, interventional radiology and picture archiving and communication system (PACs). Most of the diagnostic imaging departments are equipped with MRI 3 tesla and CT scan 128 slices. There are 33 units mammography units, most of them analogue, very few digital. There is no breast cancer screening programme, mammography is only used for diagnostic purposes in the public sector and for screening in the private sector. There is no quality control in place for all examinations notably for mammography and no practice of "double reading" the images. During our visit, "high-end" technique such as digital and 3D mammography with biopsy under suction were available, but not used because they don't have disposables (too expensive) so only tru-cut biopsy is performed under advanced mammography. CT scan services have a huge backlog. For example, obtaining a CT scan for oral cancer patient takes over few weeks.

Table 6. Available resources for diagnostic imaging and nuclear medicine

- PET/CT: 3
- SPECT: dual head / 8, single head gamma camera 1 (no SPECT/CT for hybrid imaging)
- Cyclotrons: 0 (depend on the PET tracers from India)
- Mammography units: 26 (digital and analogic)
- CT scanners: 48
- MRI: 21
- US scans widely available
- Nuclear medicine physicians: 3 (around 10-15 radiologist are practicing NM + radiology in both government / private hospitals, only reading images)
- Consultant Radiologist: 190
- Radiation/Clinical Oncologists: 45 (no separate radiation oncologists, few use RAI)
- Medical imaging technologists: Radiographers 714, Nuclear Medicine technologist 7

# **Nuclear Medicine Treatment**

NM treatment is only provided with I-131, treating thyroid cancer and thyrotoxicosis in few public hospitals that have hospital wards for radioiodine treatment. Most of the patients receive low activity treatment (up to 30 mCi) as outpatient treatment. However, there is a long waiting list for treatment of both in- and out-patient cases, and in some hospitals, this exceeds 1 year.

# **Radiation Protection**

There is no radiation protection programme in radiology and nuclear medicine. There is no use of personal dosimetry (thermoluminescent dosimeter - TLD) among the radiographers and radiologists. There is a culture of fear from radiation in nuclear medicine, and therefore the number of daily examinations is limited to reduce the exposure dose to technologist, for example, not more than 10 bone scans a day are performed. In addition, for patients who receive I-131 treatment, the urine is collected in storage tanks during the hospitalization and that limits the number of in-patient cases treated by radioiodine, due to risk of radiation exposure. During our visit, contamination by radioactive materials was found in the hot-lab of some public

hospitals, which increases the radiation exposure to the technologist and increases the background radiation of the radioisotope calibrator, which leads to decrease in dose injected to patients. There are no radiation protection standard operation procedures (SOPs) available.

# Analysis of the Apeksha National Cancer Hospital

**National Cancer Hospital** (Apeksha Hospital) is a national hospital covering comprehensive diagnosis and treatment services for cancer. It is well-equipped, but underused and the waiting list is reported from 1 to 6 months to obtain CT scans; 1 month for interventional radiology; 1 to 1.5 months for ultrasound; and 4 months for mammography. The hospital reports that PET/CT is available one day a week and only for urgent patients due to unavailability of FDGs. The number of specific procedures conducted annually is as follows: Conventional X-rays: 26000; Ultrasonography: 31074; Interventional radiology: 1418; Mammography: 6000; CT scan: 3900; MRI: 6000; PET–CT scan: 520 (40 to 60 patients per month); Endoscopic procedures: 3390.

The hospital can't accommodate all the patient needs due to lack of human resources. There is a need for more radiologists, notably female radiologists and female radiographers (to cover mammography services), interventional radiologists and nuclear medicine physicians. The nuclear medicine services are operated by inadequately trained radiologists (some of them with few weeks of training), with no certification in nuclear medicine and PET/CT procedure.

Strengths	Weaknesses
<ul> <li>Universal free health care in public hospital</li> <li>Good service coverage</li> <li>Well-structured radiology training program</li> <li>Most of the new technology is available notably "high-end" in MRI, CT scan, digital mammography and PET/CT</li> <li>Availability of private sector to cover the additional demand and decrease waiting list</li> </ul>	<ul> <li>Underutilization of new technology likely due to deficiency in financial coverage</li> <li>Deficiency in workforce notably in nuclear medicine, female radiologists and radiographers to cover mammography</li> <li>No training programme covering radiation protection education in DI/NM</li> <li>Long waiting list from 1-6 months notably for CT scan, MRI, mammography and nuclear medicine procedures</li> <li>No use of personal dosimetry</li> <li>No supervision, audit, quality control for examinations, reports &amp; radiation protection</li> <li>Limited research output</li> <li>No cyclotron available</li> </ul>
Opportunities	Threats
<ul> <li>Most of the new technology is available</li> <li>Starting a nuclear medicine curriculum based in IAEA curriculum published recently</li> <li>High volume of procedures and radioiodine treatment to gain professional experience</li> </ul>	<ul> <li>Deficiency in nuclear medicine physicians</li> <li>Unqualified doctors for some examinations due to lack of training programme</li> <li>No financial motivation in public sector to increase number of procedures</li> </ul>

Table 7. SWOT Analysis of Diagnostic Imaging and Nuclear Medicine Services

#### **Recommendations:**

### Short-term (6 to 12 months)

- Initiate formulation of a workforce development plan with support from the IAEA to identify needs for number and profile of medical and para-medical staff;
- Enforce the knowledge and practice of radiation protection in diagnostic imaging departments with the support of the IAEA, by providing training courses covering this field. Ensure continuous education in this field, as compulsory to licence and re-licence practice;
- For radioiodine treatment, develop national guideline in collaboration with the IAEA and local atomic energy commission to apply latest recommendations which will increase the number of treated patients and decrease the waiting list time significantly;
- With reference to previous needs assessment, establish a cyclotron facility for the production of PET radiopharmaceuticals to respond to the huge demand in PET/CT exams and avoid FDG importation at a very high cost;
- Assess needs for Gallium 68 Generator to start the PET/CT imaging for neuroendocrine tumours and prostate cancer;
- Increase the number of CT scan services dedicated to oncology services to increase efficiency.

# Mid-term (12 to 36 months)

- Initiate post-graduate degree programme in nuclear medicine by using the IAEA curriculum published recently, in collaboration with the University of Peradeniya and the Postgraduate Institute of Medicine at the University of Colombo. As part of it, ensure professional qualification in nuclear medicine for radiologists.
- Initiate establishment of a central radio-pharmacy to decrease cost and start new examinations by making most of the radiotracers available and affordable, provided that the national legislation allows the internal transportation of radioactive materials. For example, in Colombo they use every week 5 generators of Technetium for 5 different centres (1 generator for each centre). With central radio-pharmacy, the number of generators can be decreased to 2 and even 1 generator weekly, to cover needs of all centres.
- Develop training programme for radiopharmacist, with support from the IAEA to ensure adequate professional qualification and competencies.

# Long-term (36 months and above)

• Initiate post-graduate degree programme in radiopharmacy to meet the workforce development needs in the country and consequently, introduce *Theranostics approach* for some cancer cases, such as prostate and neuroendocrine cancers.

#### 2.8. Treatment

#### 2.8.1 Medical Oncology

Some medical oncology services are provided through 19 regional centres covering all 9 provinces. However, the services offered between provinces vary greatly, especially in the areas of histopathology, haematology, and radiation therapy. Although clinical oncologists are certified to practice both medical oncology and radiation oncology, many clinical oncologists in the public sector do not currently have access to working radiation oncology facilities. The National Cancer Institute (NCI), commonly called Apeksha Hospital is the country's one dedicated cancer hospital. The name "Apeksha" meaning "hope" is used as the patients were not comfortable with the stigma associated with the word "cancer". The hospital has the departments of Medical Oncology, Radiation Oncology and Palliative Care. The public system is structured in a three-tiered model (primary, secondary and tertiary care), however, the actual referral do not follow a prescribed path. Patients may self-refer to secondary/tertiary facilities and may choose the referral facility. Medical oncology services, as all other services, are provided by the government free of charge.

The number of patients receiving care at Apeksha Hospital and at the Teaching Hospital Karapitiya exceeds capacity. Approximately 23,000 patients are newly diagnosed with cancer in Sri Lanka each year, and approximately 16,000 new patients are seen at Apeksha Hospital. In the Teaching Hospital Karapitiya, 53 female patients were in the 25-bed ward, so each bed had at least 2 occupants. This volume results in multiple problems: i) overworked staff and inability to present all but the most difficult patients at a multi-disciplinary tumour board (*it was estimated that the routine presentation of all new cases might lead to better care up to 25% of the time*); ii) overcrowding and difficulties with infection control (*anecdotal cases of the spread of varicella due to inadequate isolation, increased fungal infections, and increased bacterial infections in neutropenic patients*); iii) difficulties in coordination of care and follow-up between the primary/district level and the secondary/tertiary hospitals. Most patients receive chemotherapy as inpatient services in the government sector; iv) overcrowding can also result in patient safety issues specially regarding chemotherapy delivery.

The lack of availability and the unreliable quality of anti-cancer medications was consistently noted as a serious and pressing problem. It was estimated that drug shortages at some time will occur in approximately 60% of patients. The Ministry of Health is responsible for the bulk purchase of medications. Each year, hospitals requests for procurement of drugs. Most WHO essential ant-cancer medication necessary were included on the list of medicines procured by the government (as well several non-essential medications). However, it was noted that shortages often exist for basic medications such as 6-MP, daunorubicin, procarbazine, and vincristine that are on the procured drug list. Dr. Sanjeeva Gunasekera has been tracking the supply of essential medications at the Apeksha National Cancer Hospital, and shortages ranged from 10% to 65%. Reasons for drug shortages are not well-documented but include: i) logistical issues (incorrect projections of needs); ii) quality (rejection of obviously poor-quality shipments and delays in replacement); iii) delays by suppliers in timely delivery of drug; and

iv) global drug shortages. Government regulations set maximum retail prices for selected drugs including some oncology drugs, but it is not clear if these regulations are being enforced and/or if they are still in place. Charitable organizations may be able to provide the shortfall in approximately 30% of patients, but this takes additional efforts from the clinical oncologists and there are delays. In the Southern province Teaching Hospital, drug shortages from the government supply were also reported to occur regularly, but drugs are purchased from local providers from the private sector in that setting.

The quality of the anti-cancer medications procured was also noted as a problem. Drugs are procured based on price, and this does not ensure quality. A specific example provided was hepatoblastoma treated with cisplatin. Although this is a tumour sensitive to cisplatin, several patients in a row had no anti-tumour response, suggesting the drug was of poor quality. Suppliers of anti-cancer drugs are requested to register with the government. Sri Lanka does not have the ability to test drugs for quality. Approval of registration of a drug supplier is done based on documentation provided by the drug supplier, rather than an independent test. It was recognised that procurement of drugs that have met FDA or EMA approval may cost more in the short-term, but currently it is preferable to provide potentially ineffective and poor-quality drugs. Patients who can afford to be seen in the private sector, may have the choice to purchase brand name drugs (as opposed to government supplied options).

There does not appear to be a functional technology review panel for anti-cancer medication procurement in order to identify the highest priority drugs to be procured and to estimate the amount of drug that needs to be procured. The amount of essential medications kept in reserve appears to be inadequate, in that supply delays lead to delays in treatment.

No formal regional oncology guidelines exist to set standards of practice for Sri Lanka. Oncologists refer to using the United States' National Cancer Centres Network (NCCN) or similar international guidelines. However, these guidelines are not formally accepted or adapted to Sri Lanka's level of resources. Resources and quality of care may differ by region but developing country-specific guidelines based on resources available should improve the quality of care and assist in planning for capacity building and resource utilization.

Local experts reported concerns regarding proper waste disposal of radioactive and biohazard material. Biohazard material is disinfected with a "bleach-like" substance and then poured down the drain. A general understanding of safe practices was understood, but there were no written guidelines, appointed safety officer, or formal training in safe handling practices and waste management.

There is a need for more formal continuing education opportunities for physicians and nurses, particularly in areas of paediatric oncology and bone marrow transplant.

There is limited research on quality of care or implementation science. Support for research is also limited. A national research foundation exists but has limited funding. Basic studies in the cancer care and outcomes could greatly help quality improvement but there are no dedicated data management staff.

Private sector health facilities consist of hospitals (profile and standards of quality of care comparable to those of the public system, although with more convenient hours, shorter waiting times, and increased availability of diagnostic tests) and clinics (either solo or group practices, providing general or specialized care). Private clinics operate on a fee-for-service model with some remuneration through insurance supplements.

All public-sector physicians including specialists are employed full-time by the Ministry of Health and are paid a monthly salary. However, the salary is considered relatively low, and many physicians engage in private practice outside working hours. Both private sector clinics and hospitals rely heavily on medical officers and consultants who are also are working in the public sector. This may also lead to a real or perceived conflict of interest if a physician refers patients from the government system to receive expensive care (which may not provide a survival benefit) in the private sector. There is also a loss of trained physicians to other countries. Therefore, the ability of physicians to supplement their income in the private sector is considered important for retention of qualified physicians.

One private clinic in Colombo (Ceylinco) reported seeing patients primarily for radioiodine therapy or radiotherapy/chemoradiotherapy (self-referred or from the government often because of long waiting times). This private clinic had very few chemotherapy-only patients, most patients received either radiotherapy or chemotherapy and radiotherapy. Chemotherapy is primarily administered as an outpatient service at Ceylinco. Full services are not provided at this centre. Physicians are not available 24 hours and emergency patients are treated elsewhere (usually the public sector). However, some private institutions provide full services including diagnostic services (e.g. lab, radiology) and pharmacies.

# **Recommendations:**

# Short-term (6 to 12 months)

- Establish a mechanism to assure adequate supply of quality oncology drugs. Supporting data collection in quantifying and understanding the reasons for these drug shortages is a critical first step in coming up with a long-term solution for this problem. This may also involve instating a review panel to prioritize the anti-cancer medications that need to be available continuously and predict the usage of these drugs and determine adequate reserve levels. Prioritization of drugs to be based on both efficacy as well as cost analysis. Consider limiting the purchase of drugs to those who have been certified by either the US FDA or EMA to ensure quality. Studies show that patients who have excessive treatment delays or incomplete treatment (< 80% of planned drug therapy) have worse survival.
- Strengthen and clarify the referral pathway for cancer patients. Establish referral processes for timely evaluation of patients who need additional diagnostic procedures (including colposcopy, diagnostic mammography, endoscopies, biopsies, and radiographic procedures). Standardise protocols, pathways, and communication formats for providers. These should include clear written plans for evaluation, documentation of medical findings, treatments provided, and plans for ongoing care. Follow-up processes should be in place so that patients referred for additional diagnostic actually receive it and this information

should be communicated back to the referring health care provider. Efforts should be made to ensure follow-up of all referrals and coordination of care between the public and private sectors. This may include patient navigation services. Sri Lanka has recently committed to developing a cluster approach to care which may facilitate accomplishing this goal;

• Review and improve safety and waste disposal procedures in the pathology, chemotherapy.

### Medium-term (12 to 36 months)

- Guidelines for the treatment of the common types of cancer should be established and standardized. International guidelines exist which could be adopted. The NCCN has developed resource stratified guidelines which could be adopted for use in the various regions within Sri Lanka that have different levels of resources. While each cancer patient has unique needs, research has shown that patients with cancer treated at facilities which has established standard of care treatment guidelines have improved outcome. Conduct appropriate staff training for adherence to such guidelines. There should be a mechanism to ensure distribution and adherence to guidelines (audits) in public and private sectors;
- Overcrowding at the Apeksha Hospital could be decreased by shifting the administration of chemotherapy to the outpatient setting. Successful models exist where patients who travel to get chemotherapy may get chemotherapy as an outpatient and the use low-cost housing overnight as opposed to using an inpatient bed. This would require a dedicated "day hospital" unit with trained nursing staff. It would also be a culture change for the oncologists, and a phased implementation strategy (starting with drugs with few immediate infusion reactions) is most likely to be successful.

#### Long-term (36 months and above)

- Each province (or other rational geographic area) should have the capacity to perform a range of cancer care services (from early diagnosis to palliative care) so that geographic constraints are not a barrier to care and the burden of care at tertiary care centres is reduced. This may involve referring patients to tertiary or a specialized cancer centre for initial evaluation and treatment planning, but the administration of the treatment plan (to include chemotherapy administration) could be conducted locally at provincial/district level. This would involve increasing capacity in both equipment and health care personnel;
- Collaborate with community-based organisations to engage them in supporting patients in order to decrease stigma and increase access and adherence to treatment for cancer. Cancer survivors may be instrumental in de-stigmatizing cancer, which may be a barrier to access diagnosis and treatment;

# 2.8.2 Radiation Oncology

According to GLOBOCAN 2018, 23530 new cancer patients are expected to occur annually in Sri Lanka. Half of the cancer patients require radiotherapy, thus annual number of cancer patients who require radiotherapy is approximately 12000. A modern linear accelerator can treat 500 patients in a year and Sri Lanka needs to operate minimum 24 megavoltage external beam radiotherapy machines to cover all patients who need radiotherapy so that same number of patients are treated in each machine. In long term (with estimated increases of number of cancer cases by 2040), the need for radiotherapy machines will increase to 33. Currently, there are 16 machines in use and 6 machines are in the phase of installation in the country (Table 8). Sri Lanka needs 47 full-time radiation oncologists, 29 medical physicists and 48 radiation therapy technologists.

Year	Annual New Cancers	Patients Need of RT	RT Units Needed <sup>e</sup>	Radiation Oncologists <sup>a</sup>	Medical Physicists <sup>b</sup>	RT Technologist <sup>c</sup>	RepairandMaintenanceStaff <sup>d</sup>
2019	23530	11765	24	47	29	48	12
2040	33052	16526	33	66	41	66	17

Table 8. Radiotherapy-related needs in the short-term and long-term

a 250 patients/year per radiation oncologist is advised.

b 400 patients/year per medical physicist is advised.

c 2 RT technicians for each RT unit.

d 1 staff member for two RT units.

e 500 patients/unit/year.

# Source: GLOBOCAN 2018: Estimated Cancer Incidence, Mortality and Prevalence

Radiotherapy is available in both public and private facilities in Sri Lanka. Currently, there are 9 radiotherapy centres Sri Lanka - 7 of them are public centres and 2 are private facilities. The major radiotherapy centre of Sri Lanka is the Apeksha National Cancer Hospital in Colombo. Both private centres are also in Colombo. Other 6 centres are all public hospitals located in the capital towns of the provinces. There is a plan developed by MoHNIM to establish 3 more radiotherapy centres, so that there will be at least one radiotherapy centre in each province of Sri Lanka. General overview of radiotherapy infrastructure is presented in Table 9.

Table 0 1	Distribution	of no diathonony	contrac and	nodiothonony	machinasi		[ anlea
Table 9.1	Distribution	of radiomerapy	centres and	radiotherapy	machines n	I SEI I	Lанка

Provinces	Capital	Population	Radiotherapy Centre	Teletherapy machines	Brachytherapy	CT Simulator
Northern	Jaffna	1,061,315	1	2	(+1)	1
North Western	Kurunegala	2,380,861	(+1)	(+1)	-	(+1)

North Central	Anuradhapura	1,266,663	1	1 (+1)	(+1)	(+1)
Eastern	Trincomalee	1,555,510	1	1	(+1)	(+1)
Central	Kandy	2,571,557	1	2 (+2)	1 (+1)	(+1)
Western	Colombo	5,851,130	3	8 (+3)	2 (+1)	3
Sabaragamuwa	Ratnapura	1,928,655	(+1)	(+1)	-	(+1)
Uva	Badulla	1,266,463	1	1 (+1)	(+1)	(+1)
Southern	Galle	2,477,285	1 (+1)	1 (+2)	(+1)	1 (+1)

\*numbers in parenthesis denote infrastructure and machines in the phase of planning or installation

Sri Lanka has 22 megavoltage external beam radiotherapy machines operational or in the phase of installation. 9 of those machines are cobalt units and 13 are linacs. Cobalt units are older than 20 years. Ministry of Health (MoHNIM) developed an ambitious project in 2012 to modernise radiotherapy infrastructure in the country (*"High Quality Radiotherapy for Cancer Patients in Sri Lanka with High Energy Radiation"*). This project targeted one radiotherapy centre in each province, by having at least one linac and one HDR brachytherapy unit, and to replace cobalt units with linacs. The project planned to establish 4 new radiotherapy centres in the provinces and install 14 linacs, 8 CT simulators and 8 HDR brachytherapy machines in the present and new radiotherapy centres.

In the first phase of the project, 9 linacs with treatment planning systems were purchased and delivered. 3 of these linacs were installed and commissioned (Apeksha, Jaffna and Batticaloa). Other 6 linacs were delivered and currently are under installation or waiting for improvements in the infrastructure to start installation. 1 CT simulator was purchased and installed in Jaffna. 3 CT simulators will be purchased for Kandy, Baticalloa and Karapitiya.

In 2018 MoHNIM started to work on the second phase of the project to construct 3 new radiotherapy centres and to install 5 more linacs, 4 CT simulators and 8 HDR brachytherapy machines. The project includes construction of the radiotherapy facilities (some buildings are already under construction), purchase of linacs, treatment planning systems, QA and dosimetry equipment, and CT simulators. Purchase of the new equipment was planned for April 2020.

Brachytherapy infrastructure in Sri Lanka is inadequate. Currently, there are only 3 HDR afterloading machines in the whole country, two in Colombo and one in Kandy. However as mentioned above, 8 new machines are being planned for installation.

The list of the radiotherapy centres and available equipment is presented in Table 10.

Center	City	Region	Туре	Teletherapy	Brachytherapy
Apeksha National	Colombo	Western	Public	3 cobalts	1 HDR – Co60
Cancer Hospital				2 linacs	
				3 linacs (ins.)	
Kandy Teaching	Kandy	Central	Public	2 cobalts	1 HDR – Co60
Hospital				2 linacs (ins.)	
Base Hospital	Jaffna	Northern	Public	1 cobalt	
Tellippalai				1 linac	
Karapitiya	Galle	Southern	Public	1 cobalt	
Teaching Hospital				1 linac (ins.)	
Anuradhapura	Anuradhapura	North	Public	1 cobalt	
Teaching Hospital		Central			
Badulla Teaching	Badulla	Uva	Public	1 cobalt	
Hospital					
Batticaloa	Batticaloa	Eastern	Public	1 linac	
Teaching Hospital					
Ceylinco	Colombo	Western	Private	2 linacs	1 HDR – Ir192
Healthcare Center					
Asiri AOI Cancer	Colombo	Western	Private	1 linac	
Center					

Table 10. List of radiotherapy centres and available equipment in Sri Lanka

\*(ins.) denotes the machines in the phase of installation

Since the number of current radiotherapy machines cannot cover the needs, there is a long waiting list especially at Apeksha Hospital. Workload of cobalt units are 150 patients daily, and the total number of daily radiotherapy patients is around 550-600 at Apeksha Hospital. Unlike cobalt machines, the maximum number of patients treated by a linac machine is usually not more than 80. A reduction in the patient load at Apeksha Hospital is expected due to opening of new centres in the provinces and installation of new machines. However, patient load should be carefully calculated and planned when replacing cobalt machines with linacs.

Currently, 2D and simple 3D planning systems are available in the radiotherapy centres operating with cobalt machines. Apeksha National Cancer Hospital has more advanced planning systems, capable of Intensity-Modulated Radiation Therapy (IMRT); Stereotactic Body Radiation Therapy (SBRT) and Stereotactic Radiosurgery (SRS).

Since no picture archiving and communication system (PACS) is available in public hospitals, CT images are transferred to treatment planning system recorded on CDs, which is not possible every time. There is an ongoing project of the MoHNIM to install PACS systems to 20 public hospitals which will significantly improve the situation.

Thermoplastic masks and headrests are widely available. However, radiotherapy requires a chain of procedures - construction of the treatment room, providing equipment and supplies including dosimetry and QA equipment, positioning lasers and patient stabilization aids. Equipment for treatment planning includes a CT simulator, treatment planning system, online radiotherapy information system, and treatment verification equipment attached to the linacs. Most of this equipment is either unavailable or not operational. Maintenance and repair of the equipment is not regularly done in many centres leading to waiting times.

#### **Human Resources**

Radiation oncology is not a separate discipline in Sri Lanka. Clinical oncologists are certified to deliver both chemotherapy and radiotherapy. However, only those clinical oncologists employed at centres with radiotherapy capacity are able to perform radiation oncology. There are 55 certified clinical oncologists in Sri Lanka, but only 28 of them are employed in centres having radiotherapy. In Sri Lanka, physicians employed in public facilities are allowed to work in private centres after working hours. Many clinical oncologists employed at the Apeksha National Cancer Hospital are working part-time in private centres in Colombo.

Since clinical oncologists perform both chemotherapy and radiotherapy, it is not easy to calculate the actual manpower used for radiotherapy. If we consider that a clinical oncologist dedicates half of the working hours for radiotherapy, then there should be 94 clinical oncologists in Sri Lanka. Current number is 55, insufficient to cover all patient needs.

Medical physicists are certified after completing a Master of Science programme in Medical Physics. Two Sri Lankan universities (University of Colombo and University of Peradeniya) provide Medical Physics programmes. There are 41 certified medical physicists, 36 of them are employed in centres with radiotherapy equipment. Sri Lanka is partner of the IAEA project "RAS6087 – Strengthening Medical Physics Services through Education and Training" and expecting to improve capacity of MPs in acquiring skills for new techniques within this project.

RTTs are graduates from the Sri Lanka School of Radiography, where both diagnostic and therapeutic radiographers are trained. Some private schools also provide education for RTTs. Education is 2 years. The first year is common to all students and therapeutic radiography students (RTTs) learn and practice only radiotherapy in the 2nd year. Currently 85 RTTs are employed in the radiotherapy centres.

There are no properly trained medical engineers available in the radiotherapy centres. Maintenance and repair service are provided though maintenance contracts. This is available for linacs but not available for old cobalt units and CT simulators. This is the main reason why some of the equipment is not operational.

After the installation of all 14 linacs, there will be a transition from 2D treatments to 3D conformal radiotherapy including IMRT and other advanced techniques. There should be proper training for radiation oncologists, medical physicists and RTTs on developing and using the new and more advanced techniques. For example, the newly established centre at Batticaloa is not operational yet, due to lack of adequate training for medical physicists.

#### **Recommendations:**

# Short-term (6 to 12 months)

• Collaborate with the IAEA for training of clinical oncologists, medical physicists and RTTs to enhance their capacity on the transition from 2D to 3D radiotherapy including IMRT;

• Share the current development and procurement plan with the IAEA and Sri Lanka College of Oncologists for review, and closely collaborate with these partners in planning for and establishment of the new radiotherapy centres, as well as upgrade of existing.

### Medium-term (12 to 36 months)

- Complete the second phase of the radiotherapy expansion project. Ensure CT simulators and HDR brachytherapy machines are included in the plan to all radiotherapy centres;
- Provide regular supply of radiotherapy auxiliary equipment: positioning aids, dosimetry and QA equipment; TLD chips, brachytherapy applicators and catheters.

# Long-term (36 months and above)

• Develop a long-term project to provide necessary infrastructure and manpower by 2040.

# **Recommendations to the IAEA**

- Support Sri Lanka on the current and forthcoming projects related to radiotherapy including planning infrastructure and workforce development;
- Provide training to clinical oncologists, medical physicists and RTTs on the transition from 2D to 3D radiotherapy including IMRT.

# 2.8.3 Surgical Oncology

The National Cancer Control Plan envisions the creation of a network and improving infrastructure and resources amongst the existing and planned cancer diagnosis and treatment facilities. Specifically, it shows intent in developing and augmenting critical surgical subspecialties to support cancer treatment and control.

Sri Lanka has created informal linkages with centres in the UK and Australia, but this is primarily restricted to training rather than sharing best practices with patient care or collaborative research. Increasing international collaborations especially with neighbouring countries like India would be an effective initiative. The recent plans of the Apeksha Hospital to work together with the National Cancer Grid of India is an important initiative. Creation of discrete "Centres of Excellence" would also ensure that each of the major cancer centres specializes in one major, complex surgical area, ensuring that expertise and infrastructure is optimally utilized. Such centre for example, is the Centre for Research in Oral Cancer situated in Peradeniya. It incorporates stakeholders from all areas of oral cancer management with international collaboration and research.

One of the problems about the current system is that cancer surgeons get transferred from one centre to another every four years. This results in a mismatch of expertise and available infrastructure, inability to create teams and importantly, prevent quality research from being undertaken. While this is a problem in all areas of cancer treatment (radiation, surgical and medical oncology), this is particularly important for cancer surgery where this prevents complex procedures from being performed, and Centres of Excellence (CoE) from being developed. Encouraging longer stints in cancer centres would enable specialization, creation

of CoEs, and centralization of services in specific centres. This would need to be balanced with the need to have adequate numbers of specialists in all centres (besides the big cities).

# **Relevant statistics**

It is estimated that 37% of patients were treated with surgery, 44% with radiotherapy and 51% with chemotherapy. There is no central database to indicate the total number of curative and palliative surgical procedures performed nationally for cancer. While individual surgeons and units maintain specific databases, these are by no means comprehensive or complete.

**Waiting times:** On average, overall waiting times for cancer surgery range between 6 and 16 weeks compared to a 3-4-week period which could be considered acceptable. This waiting time can be divided into: (a) the waiting time from presentation to a hospital to a treatment decision, and (b) from the decision-point to actual initiation of treatment. While the former is a reflection of availability of facilities for investigations and work-up(delayed dates for CT scans, biopsies etc.), the latter is a reflection of availability of qualified and trained surgeons, operating time and hospital beds. Waiting times from the decision-point for surgery and actual surgery for individual cancer centres are as follows: Jaffna (2-3 months); Anuradapura (1 month); Ratnapura (3-4 weeks). Specifically, there is a crisis in the eastern provinces not because of the infrastructure, but due to lack of anaesthesiologists and only 2 surgical oncologists.

The main reason for delays in surgery after a treatment decision has been taken is that not all hospitals have dedicated surgical oncology (SO) operating units. Only 3 out of the 9 provincial hospitals have separate SO operation units. It is apparent that surgical oncology units in all the national and regional hospitals require additional dedicated beds, enhanced operating time (more dedicated operation theatres), increased human resources, and supportive staff (anaesthesiologists, nurses etc.) to be able to offer services within a reasonable timeframe. Periodic audits to confirm adherence to target timelines on waiting times would be required.

# Human Resources

Currently, there are 18 certified surgical oncologists (SO), in the public hospitals, working in 9 provinces. There are 24 certified SO which includes the private sector/military (3 SO in the private and 3 SO in two military hospitals). Currently, there are 9 SO in training, some of them outside the country. This implies that there will be 33 SO (27 in the public sector) in the near future. In addition, there are 4 gynaecologic oncologists (GO) (plus 3 GO currently in training) who are currently working at the Apeksha Cancer Hospital and Kandy. The distribution of cancer surgeons is skewed, with the Western, Southern and Central provinces having most of the surgeons. There are 31 Oral and Maxillofacial Surgical units in Sri Lanka with over 44 consultants Oral and Maxillofacial Surgeons (OMF). In addition, there are 28 OMF surgery trainees currently under training.

It is estimated that over half of cancer patients are treated by SO and gynaecologic oncologists (GO). General surgeons and allied subspecialists (e.g. urologists, neurosurgeons, paediatric surgeons) treat the remaining. With regards to oral cancer, more than half are treated by Oral and Maxillofacial Surgeons. Sub-specialisation of Oral and Maxillofacial Surgeons to oral

cancer would contribute to reducing the burden of oral cancer treatment to other surgical specialities. Tertiary Maxillofacial Surgery units in Colombo and Peradeniya perform treatments that include microvascular reconstructions to improve the quality of life.

For a country faced with over 20,000 new patients being diagnosed every year, there is a clear shortage of certified surgical oncologists along with availability of nurses and anaesthesiologists. This shortage of qualified surgical oncologists also precludes subspecialization in individual areas of cancer surgery like thoracic, gastrointestinal, urologic, bone and soft tissue cancer surgery, which is a necessary element for excellence in surgical outcomes. On a conservative estimate, at least 35 more surgical and 6 more gynaecologic oncologists would be required within the next ten years (15 SO and 3 GO in the next 5 years), bringing the total to 62 certified surgical oncologists and 10 gynaecologic oncologists in the public sector within the next ten years.

**Education process:** undergraduate medicine, followed by 3.5 to 4 years training in general surgery. Registrars doing specialty training like surgical oncology do so for 3-4 years, partly in Sri Lanka and partly out of the country, mostly in the UK and Australia. The Postgraduate Institute of Medicine runs and monitors the programme. It governs all postgraduate training programmes. Overall, it takes between 10 and 12 years of formal education to become a specialist surgeon.

The training programme for surgical oncology is extensive, comprehensive and comparable with some of the best surgical oncology training programmes globally. The exposure to international centres treating cancers gives trainees an opportunity to observe and learn from different work environments. However, in-service training and continuous medical education could be improved with surgeons being funded by the government through academic funds to participate regularly in national and international meetings and workshops to enhance their skills and knowledge.

Oral cancer is mainly managed by Oral and Maxillofacial (OMF) surgeons in Sri Lanka. Oral and Maxillofacial surgery is a dental related speciality which offers over 2 years of training in managing patients with oral cancer and potentially malignant conditions. OMF surgeons have established collaboration with the international OMF surgery community which helps them to access high quality trainings. In terms of future training needs, a specialized training in advanced reconstruction (microvascular) will help improving the standards of treatment.

# Infrastructure

Only 3 out of 9 provincial hospitals have separate dedicated surgical oncology operation units. This is a major bottleneck to providing timely access to surgical oncology services. A strong thrust towards dedicated operation theatres for cancer surgery would improve access to potentially curative treatment in a timely manner. Frozen section is not available in many of the centres treating cancer. The workload on surgical pathologists is extremely high, which is likely to result in delays in reporting as well as lack of quality control. Dedicated surgical oncology beds and operating lists are mandatory. Support services, like frozen section and surgical pathology with reliable and timely immunohistochemistry (IHC) should be developed.

# Quality

All the certified surgical oncologists in Sri Lanka have gone through a high-quality training programme and had exposure to some of the top cancer surgical units in the UK and Australia. The Apeksha Hospital and some of the teaching hospitals have regular multidisciplinary tumour boards where surgeons participate. Clinical guidelines for management are being developed for oral and breast cancer. Guidelines for other cancers are not yet developed. More importantly, the level of implementation and adherence to guidelines is not documented. Regular audits are done only in some of the cancer centres. While some centres maintain databases of surgeries performed, formal mortality and morbidity meetings are not regularly done in most of the centres.

# **Recommendations:**

# **General recommendations**

- *Short-term (6 to 12 months):* Adapt existing resource-stratified evidence-based management guidelines for treatment of patients with cancer. The Indian National Cancer Grid guidelines may be adapted without need to develop separate guidelines;
- *Medium-term (12 to 36 months):* Increase operating theatre slots for cancer surgery in all major centres treating cancer (including all hospitals with surgical oncology units);
- Long-term (36 months and above): Promote centralization of complex cancer surgery.

# Human Resources

- *Short to medium-term (6 to 36 months):* Training and education (pre-service and inservice) motivate cancer surgeons to improve expertise, including government support for participation in international meetings/ workshops;
- *Medium-term (12 to 50 months):* increase the number of certified surgical oncologists, gynaecologic oncologists and oral and maxillofacial surgeons in the country;

# Infrastructure

- *Short to medium-term (6 to 36 months):* Increase dedicated beds for surgical patients in all centres treating cancer;
- *Long-term (36 months and above):* Create "Centres of Excellence" in specialized complex cancer surgery e.g. Hyperthermic Intraperitoneal Chemotherapy; Oral and Maxillofacial.

# Quality

- *Short-term (6 to 12 months):* Ensure mandatory review of patients in multidisciplinary tumour boards and regular audits with monthly Mortality & Morbidity (M&M) meetings;
- Short to medium-term (6 to 36 months): Adapt existing guidelines (the Indian National Cancer Grid resource stratified guidelines or the NCCN resource stratified guidelines) for management of cancers and initiate audits to evaluate adherence to guidelines;
- *Medium term (12 to 50 months)* Make data for treatment outcomes and quality care available in the public domain.

#### 2.8.4 Paediatric Oncology

Sri Lanka has a different paediatric oncology specialization than the rest of the world. Paediatric oncology is not a subspecialty under paediatrics, but it considered under clinical oncology. Residency training is coordinated by the Post Graduate Institute of Medicine (PGIM) of the University of Colombo. In the Sri Lankan residency training system for oncologists, the first 3 years of the residency programme is common for clinical oncology, paediatric oncology and hemato-oncology residents. After 3 years, residents receive another 2 years specialized training to receive a board-certified clinical oncology, at least one year of this period should be in an overseas centre of excellence. To be certified as a paediatric oncologist or hemato oncologist another 1.5 years of specialized training is required. Paediatric oncologists and hemato-oncologists are also certified to deliver radiotherapy based on their training.

Currently, there are only 2 certified paediatric oncologists in Sri Lanka, both are employed at the Apeksha National Cancer Hospital. The annual number of childhood cancers is 600-700, which is beyond the capacity of the current paediatric oncologists. Although some clinical oncologists who have a special interest in paediatric oncology help them in the management of these cases, there is still an urgent need for more certified paediatric oncologists in Sri Lanka. Main reasons for the low number of paediatric oncologists are the following: long training period to be certified which limits the interest in the specialization and the limited number of specialization slots issued by the MoHINM.

In 2019, 640 childhood cancers are recorded in Sri Lanka. Principally all paediatric patients are sent to the Apeksha National Cancer Hospital to receive chemotherapy and radiotherapy, since this is the only paediatric cancer centre. This causes several problems including transport, accommodation and long-term follow-up of patients. As a result, some patients cannot access cancer care. Establishing paediatric cancer centres (units) in other large cities, preferably in Jaffna and Kandy, will improve access to paediatric cancer care.

Paediatric cancers are different then the adult cancers. This requires a different policy, approach and management. There is no specific policy in Sri Lanka for paediatric cancer, including diagnosis, treatment and supportive care, including integration of paediatric cancer survivors to the society. Sri Lanka should develop a comprehensive long-term paediatric cancer policy.

#### **Recommendations:**

#### Short to medium-term (6 to 36 months)

• Collaborate with the International Society of Paediatric Oncology, WHO and IAEA for training of paediatric oncologists and review of their current formal education programme;

# Medium to long-term (12 to 50 months)

- Provide more positions for paediatric oncologists in the public hospitals;
- Develop a comprehensive long-term paediatric cancer policy;
- Establish paediatric oncology centres in other main cities, preferably in Jaffna and Kandy.

### 2.9. Palliative Care

#### **Policy Framework**

Sri Lanka does not have a National Policy on Palliative Care. Palliative care is identified as necessary continuum of care in several health policy documents: National Policy for Control of Non-communicable Diseases (2010); National Cancer Control Plan (2015); National Elderly Health Policy (2017). Palliative care is also prioritized activity in the National Multi Sectoral Action Plan for the Prevention & Control of Non-Communicable Diseases (2016-2020). In addition, Sri Lanka Health Master Plan (2016-2025) provides the vision for a comprehensive palliative care programme integrated into the mainstream health care.

Draft of the National Strategic Framework for Palliative Care in Sri Lanka has been developed and currently is available for input and review by relevant stakeholders. This policy document is expected to be finalized in the next couple of months.

### **Palliative Care Needs and Services**

Sri Lanka has a population of about 22 million. Crude death rate for Sri Lanka in 2019 is 6.717 deaths per 1000 people, or, approximately 148,000 deaths a year. The total number needing palliative care is estimated as 60% of all deaths, or 89,000 people a year, majority of them affected by non-communicable diseases. With the ongoing rapid ageing of the population, the number of patients needing palliative care will predominantly be elderly terminally ill.

There are approximately 23,000 new cancer cases in Sri Lanka annually. The exact number of patients in need of palliative care is not available. Available data show more than 70% of oral cancer, more than 50% of cervical cancer and more than 30% of breast cancer case presenting at late stage. With the available data on incidence and cancer stage, an estimate is that there are more than 15000 cancer patients in need of palliative care at any point of time. Currently, out of all cancer and non-cancer patients needing palliative care, less than 1% have access to palliative care services. Very few of the patients with diseases other than cancer in need of palliative care.

In the Government sector, formal palliative care service is available only in eight hospitals, including 4 teaching hospitals. All of them are outpatient clinics and in-house consultation services. All except Apeksha Hospital run palliative care clinics only once a week. Number of patients referred to palliative care clinics is low in all these hospitals except Apeksha Hospital. This hospital has the full-fledged outpatient services six day per week. There are no dedicated inpatient beds or home-based services available in the government sector. Karapitiya Teaching Hospital (Galle) is planning to open an inpatient palliative care unit with 30 dedicated beds by early 2020. This will be the first palliative care inpatient facility in the Government sector. All the staff for palliative care is assigned on ad-hoc or work on voluntary basis.

Inpatient beds and home-based services are made available in various sites by the civil society organisations. There are about 7 home-based programmes and 9 hospices. Some of these hospices and home-based units collaborate closely with the public hospitals in their region (for example Shantha Sevana in Colombo; Hospices and Home Care programmes by Cancer Care

Association in Mathara and Anuradhapura; Home Care programme by CANE in Jaffna). Currently, these are all informal arrangements. There is no uniformity in standards or quality of services between the initiatives by these various civil society organisations. They also provide supportive care to cancer patients. Typical example is the social and financial support offered by the Indira Cancer Trust in Colombo and the Cancer Care Association in four districts. The Indira Cancer Trust plans to start a Children's Palliative Care unit in Colombo in 2020. Sri Lankan Cancer Society is running a hospice in Colombo for patients from Apeksha Hospital and supports the construction of the inpatient unit in Karapitiya Teaching Hospital. In the private sector, only one hospital (Asiri Surgical Hospital) has a palliative care unit.

### **Palliative Care Stakeholders**

National Cancer Control Programme takes the lead role in the development of palliative care services in the Government sector. Civil society organisations (CSOs) are also involved in delivery of palliative care in the country. Various CSOs conduct trainings, awareness raising activities and run a limited number of hospices and home-based care programmes. Task Force for Palliative Care of the Sri Lanka Medical Association and the Palliative Care Association of Sri Lanka have been playing important role in capacity building and policy making in collaboration with the National Cancer Control Programme.

### **Financing Palliative Care Services**

The eight recently started palliative care clinics in the Government sector depend on availability of hospital funds. Karapitiya Teaching Hospital is now constructing a new inpatient block for palliative care with major support from the local community. Most of the limited number of hospices and home-based care services are in the non-governmental sector and supported by donations from the community.

# Availability, Accessibility and Consumption of Opioids

Medical Supplies Division of the Ministry of Health (MoHNIM) is the national authority for stocking and dispensing morphine in the country. Oral Morphine, Fentanyl Patches and Tramadol (Tablet and Injection) are available, in addition to Injection Morphine and Pethidine.

All doctors with a licence to practice allopathic medicine can prescribe opioids. Palliative care units or oncology units can give prescription for one month. Other specialists can prescribe for two weeks. Any doctor can give a prescription for one week. Stocks of opioids are available only in few major hospitals and the limited number of state pharmacies. Supply of opioid drugs gets disrupted often.

Sri Lanka has an essential drug list in which both injection and oral morphine are included. Tramadol is also in the list. But unlike the other drugs in the essential drug list, morphine is not currently stocked in the secondary level hospitals and primary health centres.

#### **Palliative Care Education and Training**

Postgraduate diploma programme in palliative medicine has been initiated in 2018 by Post Graduate Institute of Medicine at the University of Colombo. The first batch of 13 doctors successfully completed training in 2019. The second batch of 15 doctors is now undergoing training. This one-year full time programme has the potential to address the mid-level trained medical workforce requirements in palliative care. There is no similar attempt to address the basic training needs for consultants. There have been a good number of sensitization and basic training programmes for doctors, but the structure and content vary.

National Cancer Control Programme, in collaboration with the Asia-Pacific Hospice Network had a "Master Trainer Programme", 6 one-week sessions over three years. A total number of 38 doctors and nurses were trained through this programme. The College of General Practitioners of Sri Lankan Medical Association (and later the Palliative Care Association of Sri Lanka) have been offering basic trainings to doctors in collaboration with external agencies. Around 500 doctors in various provinces have been trained through this scheme. Lien Collaborative had recently completed a 35-hour team-based training programme for doctors and nurses. 35 doctors and 22 nurses attended. All these trainings are a tiny fraction of the need to train 14,000 doctors at the grass roots level.

There are no structured or basic training programmes available for nurses. A few nurses had attended combined training programmes with doctors, as mentioned above. Palliative Care Association of Sri Lanka had done basic training programmes for nurses. 40 nurses attended a two-day programme. Teaching Hospitals with palliative care programmes have also started doing one to two-day workshops to sensitize and train doctors and nurses. Post-basic course for nurses at the Nursing College is being planned. Curriculum is almost ready. The programme includes 6 months in-service training and 6 months follow up assignments. It is expected to be launched in 2020. Undergraduate Medical and Nursing curricula do not include palliative care.

National Cancer Control Programme together with several civil society organizations have initiated programmes to train community volunteers. Training manuals in Sinhalese and Tamil have been published. The aim is to equip family carers and volunteers for basic skills in physical, emotional and spiritual care and to address issues related to referral and self-care.

#### **Recommendations:**

#### **Priority recommendation**

• National Palliative Care Strategy to be finalised and endorsed. An action plan integrating palliative care into mainstream health care, with emphasis on primary health care to be generated as a matter of priority. A technical committee under the National Cancer Control Committee can be appointed for this assignment.

# Short-term (12 months)

• Consolidation and expansion of the existing palliative care services in the Government sector to be done. This will mean allotment of regular permanent staff, basic budgetary

provisions and ensuring uninterrupted supply of necessary medicines including opioids. This recommendation can be operationalized through:

- An orientation programme for oncologists and other consultants to ensure that they play a more active role in palliative care in the hospital settings;
- Under the auspice of the NCCP office, conduct a national workshop with key stakeholders to review the existing procurement and supply process of medicines and associated regulations;
- Develop an opioid drug procurement calendar in the hospitals to better estimate usage of opioid analgesics and place orders in time to ensure uninterrupted supply. An annual estimate can be made based on the estimated number of incurable cancer patients expected to register each year. With an average of 60mg/day consumption per patient and average of 100 days of analgesic support a year, 6 g of oral morphine will be needed per patient registered. If the expected number of patients next year is 100, the amount of oral morphine (or equivalents) to be ordered will be 600 g.
- Guidelines and standards for inpatient services/hospices and home-based care services to be urgently established. An accreditation system for NGO managing palliative care services to be established based on compliance to these guidelines and standards. Accredited services to be linked to the Government hospitals in the region for mutual support and complementing services. Such a system of accreditation-based collaboration will ensure accountability and quality of services in the civil society sector;
- Terms and conditions for collaboration between civil society organizations and Government hospitals in developing palliative care services need to be formulated;
- Sensitization programmes (2-5 hours) and basic training (15-70 hours) for doctors and nurses by various agencies to be continued. Non-governmental organisations and professional organisations can continue to play a major role in this area. Palliative Care section in WHO's PEN manual can be used for this sensitization programme. Guidelines for Palliative Radiotherapy by the IAEA and Foundation Course Manual by WHOCC IND135 can be used for setting up a basic training programme;
- Faculty at Post-Basic College of Nursing need to be trained to run the proposed Post Basic Diploma in Palliative Nursing. This can be done by twinning the nursing college with an experienced overseas training partner;
- Structured training programmes for community volunteers as recommended by the WHO to be established. Training manuals in Tamil and Sinhalese published by Palliative Care Association of Sri Lanka can be used for 3 hour and 16-hour structured training.

# Long-term (2 to 10 years)

• Integration of palliative care services at the three levels of health care. This will include establishing links between primary health care and home-based services to address basic issues of patients with advanced diseases; establishing middle-level palliative care physician-led outpatient and inpatient services in secondary hospitals; and establishing consultant-led palliative care units in tertiary hospitals;

- Develop and implement in-service basic training in palliative care to all primary health care staff and ensure availability of all medicines in the essential drug list including opioid at the primary health care level;
- Develop home-based care services attached to primary health centres. Public Health Nursing Officers can be oriented and entrusted with this task. WHO publication "Palliative Care integration into Primary Health Care" can be used as guidance;
- Consider developing consultants in palliative medicine. The process will take up to 10 years to bring specific results 2 years to complete the process of starting the course; 3 years for the first batch of candidates to successfully complete the course; 2 years of domestic and another 2 years of foreign training for the candidate to take the board examination;
- Introduce palliative care in the undergraduate medical and nursing curricula;
- Establish implementation research programmes in palliative care, not only at tertiary health care level, but under other cross-cutting disciplines Public Health, Nursing, Psychology etc.

# 2.10. Civil Society

Sri Lanka has a long history of civil society involvement in cancer care. Religious groups have been involved in temple-based support activities for cancer patients in many areas. Cancer Care is an area which elicits good interest and enthusiastic support from the civil society organizations in Sri Lanka. Various civil society organisations are involved in activities related to cancer care. These include awareness work, provision of information and guidance, supportive care for patients on treatment and palliative care. Most of the cancer care activities of the civil society organisations in the country are linked to patient care in the public sector hospitals. Nevertheless, activities of the civil society organizations are not always synchronised with the National Cancer Control Programme (NCCP). There are no guidelines and standards available for the activities provided by the civil society organisations.

There are several registered civil society organisations taking a role in the awareness, early detection, supportive care and palliative care activities. The key organisations are listed below.

# Sri Lanka Cancer Society

Sri Lanka Cancer Society is probably the largest and oldest CSO focussing on prevention of cancer and support for cancer patients in the country. The organisation has six branches in the country (Colombo, Moratuwa, Anuradhapura, Kandy, Galle, and Batticaloa). Activities/events are mainly linked to cancer hospitals in the public sector. The level of activities and range of projects vary from branch to branch. The Society has specific subcommittees on Cancer Homes providing accommodation for patients, Hospice Services for patients with advanced diseases, Public Education for awareness raising & Relief/Rehabilitation providing supportive services.

Activities include cancer awareness campaigns, supporting early detection activities of local Teaching Hospitals, transport services for patients to access treatment, accommodation for patients/families and financial support for patients mainly to cover the cost of diagnosis services. Sri Lank Cancer Society has been running a hospice supporting incurable cancer patients discharged from the Apeksha Hospital.

### Cancer Care Association of Sri Lanka

Cancer Care Association of Sri Lanka started few years ago, as a district level programme in Anuradhapura and later expanded to other regions in the country. In addition to building palliative care services (Cancer Care Hospice in Anuradhapura, Home Based Palliative Care Units in Anuradhapura and Galle and the recently opened Institute of Palliative Medicine in Mathara), Cancer Care Association has also been organizing awareness raising activities aimed at prevention of cancer and reducing stigma and discrimination.

School-based programmes are also being organized to increase awareness. The focus of schoolbased campaigns is on preventing the use of tobacco/smoking and sensitization on breast and cervical cancer prevention. Activities in the community include "Cancer Walks", Distribution of Pamphlets and Free Breast Examination Clinics.

Cancer Care Organization publishes the "Sarana" magazine annually, which is the first and only Sinhala magazine about cancer in Sri Lanka.

Supportive care for cancer patients on treatment include provision of food, and financial support covering cost of transportation and some of the diagnosis services.

### Indira Cancer Trust

Indira Cancer Trust is a relatively new civil society organisation and has been established as an important stakeholder. Indira Cancer Trust maintains the only cancer helpline in the country. This 7-days-per-week telephone service is operated by trained volunteers to provide guidance, provide information about cancer and early detection, connect clients to local and national resources (support groups; transportation services; accommodation etc.), offer counselling and emotional support to patients and offer financial counselling regarding costs for treatment.

This organization also provides services for cancer patients in the Colombo district. Through the "breast prosthesis project", they provide free of charge prosthesis for breast cancer patients. Through the "livelihood development programme" they provide financial assistance and transport allowances.

Indira Cancer Trust has been organising outlets for selling products made by patients, relaxation therapy sessions for patients and families, counselling sessions for patients, education scholarships for children of cancer patients and financial and emotional support to children with cancer.

The organisation is planning a mobile mammography unit and a major paediatric centre in Colombo to support children with cancer and their families. Both projects are expected to be launched in 2020.

# Cancer Aid for North and East (CANE) - Sri Lanka

CANE is a 25-year-old UK based charity supporting cancer patients in North and East Sri Lanka. The organisation is involved in community-based cancer awareness and education

activities in addition to home-based palliative care and hospice care. Palliative care services are also used as a base for cancer awareness and education activities.

CANE also financially supports cancer care activities by other organisations like Batticaloa Cancer Society in the North and East regions. Activities include support for biopsy and cancer diagnostic services through private laboratory services, nutritional support of cancer patients, transport from Batticaloa to Maharagama (Colombo) for treatment and providing financial assistance to patients with low socio-economic status.

# Palliative Care Association of Sri Lanka

National Organisation for Palliative Care focusses mainly on training and promotional activities for policy development. They also run a nutritional support programme for cancer patients, in addition to community-based palliative care programme.

### Sathya Sai International Organisation

The Sri Lankan unit of the International Organisation currently runs the Sri Sathya Sai Suva Sevana Hospice near Colombo and a nearby elderly home. They also have various volunteer activities in the community. This organisation with a total of 79 Sathya Sai Centres and Sai Devotional Groups, supervised by five coordinating committees, has a potential to be involved in cancer care over a wide geographical area.

### Shanthi Foundation

This Australia-based charity is building a specialist Palliative Care Hospital for patients with advanced cancer and Chronic Kidney Disease in Anuradhapura. This is probably the only organisation focussing on palliative care to patients with advanced kidney diseases.

#### **Recommendations:**

# Short to medium-term (within 24 months)

- Cancer care activities of the civil society organisations need to be accounted for and matched against the aims and objectives of the National Cancer Control Programme. This can be done through a three-step procedure for synchronisation:
  - A national workshop for the civil society organisations to familiarise them with the national cancer control programme and to identify good examples of collaboration;
  - Establishing a template for the civil society organisations to report their activities and align with the objectives of the national cancer control programme;
  - Annual review of activities of the civil society organisations involved in cancer care
- NCCP to develop guidelines and standards for the activities provided by the civil society organisations. An accreditation system should be carried out, in particular for CSOs involved in managing palliative care services (*same as under palliative care*).

### 2.11. Radiation Safety Considerations

#### Summary of the status of the regulatory infrastructure for safety in Sri Lanka

#### (based on April 2019 IAEA advisory mission)

#### National Policy and Strategy for Radiation Safety

The current legislation for radiation safety has elements of a national policy and strategy for safety. However, the government has not yet established a separate document defining the national policy and strategy for safety, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles, as required in GSR Part 1 Rev. 1.

#### Legal Framework

Sri Lanka Atomic Energy Regulatory Council, SLAERC (national regulatory body) and Sri Lanka Atomic Energy Board, SLAEB (organization promoting nuclear technologies) report to the same Ministry (Ministry of Power, Energy and Business Development).

SLAERC recognized that although in its decision-making process there is no interference from the Minister, in the long-term formal legal arrangements through the amendment of the Act should ensure separation between SLAERC and SLAEB.

SLAERC is authorized to draft regulations that are issued by the Minister. The IAEA team was informed that in practice there is no possibility of the Minister's interference in the process of establishing regulations in Sri Lanka.

However, in the light of IAEA safety standards, in case an agency of Government is itself an authorized party operating an authorized facility or conducting authorized activity, the regulatory body shall be separated from the authorized party. Moreover, the government shall ensure that the regulatory body is effectively independent, in making decisions relating to protection and safety, of persons and organizations using or promoting the use of radiation and radioactive material, so that it is free from any undue influence by interested parties and from any conflicts of interest; and shall ensure that it has functional separation from entities having responsibilities or interests that could unduly influence its decision making.

#### **International Instruments**

Sri Lanka has made a political commitment with regard to the Code of Conduct on the Safety and Security of Radioactive Sources; has notified the IAEA of its' intention to act in accordance with the Guidance on the Import and Export of Radioactive Sources; and has made available its responses to the Importing and Exporting States Questionnaire.

Sri Lanka has not yet notified the IAEA of its commitment to implement the Guidance on the Management of Disused Radioactive Sources (2018).
Sri Lanka is not yet a party to the Joint Convention for the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management. Sri Lanka has disused sources on its territory that should be managed safely. The IAEA team was informed that the adherence process will be initiated shortly.

### Staffing and Competence of the Regulatory Body

SLAERC should establish a training programme to develop the necessary competence and skills of staff of the regulatory body, as an element of knowledge management. SLAERC is still working towards employing enough qualified and competent staff, commensurate with the nature and the number of facilities and activities to be regulated, to perform its functions and to discharge its responsibilities.

The documented Newly Recruited Scientific Officers Training Programme is in place for a total length of 26 weeks out of which only 1.5 week are classroom lectures and the rest is a practical training including case studies, demonstrations and technical visits. The IAEA team was informed that the inspectors participate in inspections during this practical training. The training programme may need to be reviewed to include the national regulations, to ensure the balance between the academic and hands-on activities (for example in the area of medical exposures).

The IAEA team observed that the training in medical uses of radiation is insufficient for the inspectors conducting inspections on radiotherapy facilities and activities.

## National Inventory of Radiation Sources

The national register of Radiation Sources is maintained through IAEA Regulatory Authority Information System RAIS 3.4 that has been used since March 2018. The system was established with the IAEA assistance. Scientific Officers of the SLAERC were trained on the use of the RAIS 3.4 database.

SLAERC continues updating the source register and intends to maintain it subsequently. Until now, approximately 650 radioactive sources are reported in the database. Remain still about 10 % of all existing radioactive sources and about 950 X-ray generators that still need to be included in the register.

All Category 1 and 2 radioactive sources are under regulatory control and registered in the national source database.

## Authorization, Review and Assessment

SLAERC applies graded approach through varied duration of the license validity commensurate with radiation risks associated with the facility or activity (Schedule of Order No 1924/27 - 2015). The validity of licenses varies from 1 to 3 years. An inspection is conducted before each instance of issuing a license of a new facility or activity. No inspection is required for license renewals although not precluded. The IAEA team was informed that there is no coupling between licensing periods and inspection frequency.

### Inspection

Although SLAERC has developed some inspection forms, it does not have a comprehensive inspection programme of facilities and activities including formal written inspection procedures. The existing inspection forms do not cover all the necessary regulatory requirements and license conditions to be verified on inspections.

The inspection forms for medical X-ray activities include quality control activities that SLAERC inspectors are expected to perform for hospitals.

Currently, the general diagnostic medical and dental equipment is inspected regularly by SLAERC inspectors. Such equipment must be fit for its purpose and meet rigorous technical standards.

SLAERC is performing verification of the technical quality of equipment for regulated practices as part of regulatory inspections.

Periodic quality control and review of performance of medical sector's equipment against rigorous technical standards is to be performed by the licensees or external service providers.

## 2.12. Radioactive Material Security Considerations

### Legislative and Regulatory Framework

Sri Lanka Atomic Energy Regulatory Council (SLAERC) established with promulgation of Sri Lanka Atomic Energy Act No. 40 of 2014, is responsible to conduct regulatory programme in the country. Sri Lanka has expressed its commitment to the IAEA regarding adherence to the Code of Conduct on Safety and Security of Radioactive Sources and its Supplementary Guidance on the Import and Export of Radioactive Sources in 2016.

SLAERC has developed and approved national radiological theft response code that is already being implemented, whereas, regulations on safety and security of radioactive material during manufacture, use and storage are presently in finalization and approval stage, the gazette notification of these regulations is expected in 2020.

### General Overview - implementation of security measures at radioactive material

In order to have a general overview of the implementation of security measures at radioactive sources, the IAEA representative from Division of Nuclear Security (attending the imPACT mission) was invited to visit National Care Institute, Maharagama, Colombo, Ceylinco Healthcare Services, Colombo and Karapitiya Hospital, Galle.

During the visit it was informed that all of the category 1 radioactive sources available in Sri Lanka (includes radioactive sources used in medical, industrial irradiation and research) have been security wise upgraded through Sri Lanka–USDOE cooperation programme. The security upgrades include installation of CCTV surveillance systems, intruder alarm systems, access

control systems, robust doors, delay barriers and radiation detectors. The implementation of these security upgrades was physically witnessed at above referred hospitals.

In addition to aforementioned facilities, physical protection upgrades have also been implemented at central storage facility (for radioactive material) established and supervised by the Atomic Energy Board under the same project. All locations are connected with local as well off-site (central) security alarm monitoring stations. The Special Task Force (STF) established in collaboration with police has the responsibility to respond in security events involving radioactive material.

## Meeting with Regulatory Council (SLAERC)

A meeting between IAEA staff and the regulatory council was also convened on October 31, 2019. The objective of the meeting was to highlight key actions and issues that should be addressed in order to further enhance the collaboration between Govt. of Sri Lanka and the IAEA. The Director General, SLAERC informed that the regulatory council has developed a comprehensive safety and security inspection program to ensure implementation of safety and security measures at all radiation facilities. He further mentioned that staff from regulatory council, the operator, as well as staff from other stakeholders have been participating and benefiting from the IAEA's training activities in radiation safety and security. The IAEA staff reported on IAEA's future trainings opportunities, meetings, conferences and other various fora and highlighted their importance from the prospective of information and experience exchange.

The counterparts were encouraged to participate in the above referred trainings to benefit from such experience exchange opportunities, conduct national needs assessments in the area of nuclear security and update the country's Integrated Nuclear Security Support Plan (INSSP) and explore possibilities for IAEA's support and assistance in this regard.

Based on overview of safety and security framework as well as site visits conducted during the mission; following are some key recommendations to be considered by Govt. of Sri Lanka towards improvement of national safety and security framework:

### **Recommendations for Radiation Safety and Security of Radioactive Material:**

- Radiation safety regulations and regulations on security of radioactive material should be finalized and promulgated;
- Safety and security culture awareness should be raised among health professionals and other relevant personnel;
- Availability of dosimetry services and health surveillance programme for radiation workers should be ensured (occupational radiation protection);
- Proper functionality and adequate operation of security systems installed at high activity radioactive sources should be ensured;
- Maintenance and sustainability program for continued operation of security systems in future should be developed;

- The government should consider expressing its political commitment to the supplementary guidance to the Code of Conduct on the Management of Disused Radioactive Sources;
- Detailed capacity and training needs assessment should be conducted to develop a strategy to adequately respond and handle challenges associated with enhancement of related infrastructure;
- Participation in training programmes as well as in various other forums offered by the IAEA on nuclear safety and security of radioactive material is highly encouraged for capacity building as well as for exchange of experience and information;
- The Government should continue follow-up actions on recommendations from the IAEA advisory mission for radiation safety conducted in January 2016.

### Priority Recommendations for Radiation Safety and Security of Radioactive Material:

• The Radiation Safety and Security Regulations should be finalized and promulgated on a priority basis;

### Annex 1: Mission Agenda

# FINAL MISSION AGENDA

## imPACT Mission to Sri Lanka, 28th October to 02nd November 2019

Tentative Time	Activities	Responsible NCCP Officer/ Presenter	Venue, Logistical Requirements
18.00-21.00	Sunday 27 October         Mission Briefing (all national focal team and international experts)		
	Monday 28 October Inauguration Meeting		
09.00-09.10	Welcome Speech & Objectives	Dr Janaki Vidanapathirana - Director National Cancer Control Programme (NCCP)	Venue GF 02 Hall Hotel Galle Face Colombo 03
09.10-09.30	Overview of Sri Lankan situation of Cancer Control and Prevention & Role of National Cancer Control Programme	Dr Sudath Samaraweera Chief Epidemiologist (Former Director NCCP)	
09.30-09.45	Overview of Objectives and Methodology of imPACT Review	Dr Suraj Perera (CCP/NCCP)	
09.45-09.55	Address by Section Head Cancer Control Review and Planning Section, Division of Programme of Action for Cancer Therapy (PACT) Head of International Review Team	Ms Geraldine Arias De Goebl	

09.55-10.05	Address by Representative of NPO (Evid office Sri Lanka	ence Synthesis) WHO Country	Dr Olivia Nieveras (Public Health Administrator (WHO Country Office Sri Lanka)	
10.05-10.15	Address by Director General of Health Se	rvices	Dr Anil Jasinghe	
10.15-10.25	Address by Secretary Ministry of He Medicine	ealth, Nutrition & Indigenous	Ms Wasantha Perera	
10.25-10.30	Vote of Thanks		Dr Udaya Usgodaarachi CCD/ NCCP	
10.30 -11.00	End of Inauguration			
11.00-11.30	An Overview of National Cancer Ca Programme	re Dr Suraj Perera (CCP/NCCI	2)	
11.30 - 13.00	Presentations by national experts	berts Director, National Cancer Control Programme (NCCP) thirana Samaraweera Chief Epidemiologist, Former Director (NCCP)		
	National CancerDr Janakicontrol planningVidanapathirana& coordination			
	National CancerDr Sudath Samaraweecontrol planning&& coordination			
	Cancer registry Dr Suraj Perera & surveillance	Consultant Community Phy	Consultant Community Physician (CCP), NCCP	
	Prevention & early detectionDr Udaya Usgodaarachchi	Consultant in Community E	Dentistry /NCCP	

	Dr Loshan Moonasingha	CCP – Family Health Bureau
Diagnostic imaging & nuclear medicine	Dr Uditha Kumarasena	Consultant Radiologist, Apeksha hospital
Pathology & laboratory	DrPriyangi Amarabandu	Consultant Pathologist, Apeksha hospital
medicine	Dr Lalindra Goonaratne	Senior Lecturer in Haematology
	Dr Rajitha Samarasingha	Consultant Chemical Pathologist, Apeksha hospital
Surgical oncology	Dr Jayamal Ariyaratne	Consultant Oncosurgeon, TH Karapitiya
Medical oncology, radiation oncology & Paediatric oncology	Dr Sanjeewa Gunasekara	Consultant Paediatric Oncologist, Apeksha hospital
Palliative care	Dr Sujeewa Weerasingha	Consultant Oncologist, Apeksha hospital
Radiation safety and security infrastructure	Mr. Athula Wijekumara	Chief Medical Physicist, Apeksha hospital

	WHO Country Office	Dr Nalika Goonawardena	NPO- Evidence Synthesis		
13.00 - 14.00	Lunch Break at th	e hotel			
14.00 - 16.00	Small Group Me parts Team A (cancer of NCD and Env & O Team B (diagnos Team C (cancer of Team D (Palliation	etings - International exp control planning; prevention OH) also participate for the is and treatment) registry) ve care	perts & Sri Lankan counter on and early detection) Director is discussion	Team A - Dr Saddarama Team B - Dr Suraj Perera Team C - Dr Nirmala Team D - Dr Sachintha	Venue- Hotel Breakout rooms
18.00-21.00	Team debriefing	on preliminary findings		All	Hotel
	Tuesday 29 Octo	ber (Colombo-site visits)	)		
8.00-9.00	Security Briefing	g by UN Security Coordin	nator		Hotel
9.00 - 1.00	Team A Cancer of	control planning; preventio	on and early detection		
8.30	Departure from	Hotel			Site visits
09.00 to 10.00	Family Health B	ureau: 231 De Saram Pl,	Colombo 01	Dr Saddharama Dr Kalpani /Dr Thanuja	
10.00 to 11.00	Epidemiology U	nit: 230 De Saram Pl, Colo	ombo 01		
11.00 to 12.00	<b>Private cancer e</b> Cancer Early Det	arly detection centre Lan ection Centre Narahenpita	nka Hospital Narahenpita / n		
11.30-13.30	Meeting with DI	R NCCP on feedback reg	garding national plan		

		Dr Janaki/ Dr Camacho	
9.00 - 1.00	Visit to National Cancer Institute, Maharagama	Dr Priyantha Wijesinghe	Apeksha Hospital
8.00	Departure from Hotel		(NCI Maharagama)
	Team B, C & D together Departure from Hotel in a one vehicle		
09.00 to 10.00	Team B, C & D meet Director, D/Director & relevant Consultants & Medical Officers @ Directors office		
	Team B (Diagnosis and treatment) (site visit)		
10.00 to 10.30	Radiology Department PET Scan Unit		
10.30 to 11.00	Radiotherapy Unit	Dr Suraj Perera/Dr	
11.00 to 11.30	Radio Iodine Unit	Priyanuta wijesingne	
11.30 to 12.00	Pathology Unit		
12.00 to 12.30	Paediatric Oncology		
10.00 to 12.30	Team C (Cancer registry) Hospital-based Cancer registry - NCI/M, new initiatives of IT interventions happening at NCI Team D (Palliative care)	Dr Nirmala/Dr Chulaka Jayaweera	

10.00 to 10.30	Palliative care consult service NCI/M,		
10.30 to 11.00	Paediatric palliative care,		
11.30 to 12.00	Shantha Sevana Hospice		
12.00 to 12.30	Indira Cancer Care Trust	Dr Sachintha/Dr Thusitha/Dr Ruchira	
12.30 to 13.00	Cancer Care Association		
1.30 - 2.30	Lunch at WHO country office (Whole group)		WHO Country Office
02.30 - 4.00	Team A Meeting with insurance companies	Dr Saddharama Dr Kalpani /Dr Thanuja	WHO Country Office
02.30-04.00	<b>Team B</b> Diagnosis and treatment Visit to a private cancer hospital in Colombo (Asiri AOI Oncology Centre) & Ceylinco Cancer Care Centre	Dr Suraj Perera/Dr Priyantha Wijesinghe	Private hospital
02.30-04.00	Team C (Visit to National Cancer Control Programme Cancer registry)	Dr Nirmala/Dr Chulaka Jayaweera	NCCP office
02.30-04.00	<b>Team D</b> – Palliative care Meeting – Palliative Care Association, SLMA Palliative care and End of Life Care Task Force, Professional colleges	Dr Sachintha/ Dr Thusitha/Dr Ruchira	SLMA Office
15.00	Courtesy visit to UN Resident Coordinator (Team Leader and WHO WR a.i)		

16.30 - 18.00	Rest period	
18.00 - 19.00	Team Debriefing: Critical findings of the day; overview of agenda for next day	
19.00	Individual report writing	
	Wednesday 30 October (Field visits to three provinces)	
6.00 a.m. – 6.00 p.m. Team A Departure Hotel @ 06.00 am	Team A         (cancer registry; early detection; diagnosis, treatment & palliative care)         Southern province	
Team B Departure Hotel @ 05.30 am	<ul> <li>visit to provincial hospital; visit to primary health clinic involved in prevention and screening; hospital-based cancer registry; meetings with teaching staff; meetings with hospital management</li> <li>visit Palliative care unit,</li> <li>Visit Cancer Treatment Centre Southern Province - TH Karapitiya</li> <li>Visit to Faculty of Medicine Ruhuna – Nuclear Medicine, Pathology units</li> <li>Focus Group Discussion with PHC providers involved in prevention and screening</li> <li>Visit to a PHC</li> </ul>	Dr Suraj Perera/ Dr Chulaka Jayaweera
	<ul> <li>Team B (cancer registry; early detection; diagnosis and treatment)</li> <li>Central Province</li> <li>Visit to provincial hospital; visit to primary health clinic involved in prevention and screening; hospital-based cancer registry; meetings with teaching staff; meetings with hospital management</li> </ul>	Dr Udaya Usgodaarachin/Dr Mangala

Team C Departure Hotel @ 06.00 am	<ul> <li>Visit Nuclear Medicine Department – Faculty of Medicine, University of Peradeniya</li> <li>Visit Centre for Research on Oral Cancer (CROC) – University of Peradeniya</li> <li>Visit to Oro Maxillo Facial (OMF) Unit, TH Peradeniya</li> </ul>		
Ву 19.30	<ul> <li>Team C (cancer registry; early detection; diagnosis and treatment)</li> <li>North-western Province <ul> <li>visit to provincial hospital; visit to primary health clinic involved in prevention and screening; hospital-based cancer registry; meetings with teaching staff; meetings with hospital management</li> <li>Visit to Cancer Treatment Centre Central Province - TH Kurunegala (Treatment centre without radiotherapy)</li> <li>Focus Group Discussion with PHC providers involved in prevention and screening</li> <li>Visit to a PHC in the same province</li> </ul> </li> </ul>	Dr Sachintha/Dr Nadeeja	
	Thursday 31 October (Colombo)		
9.30 - 10.30	Meeting with Head of Regulatory Authority (Mr. Muhammad (NSNS), Ms. Arias de Goebl PACT)	Dr. Anil Ranjit (Head) Deputies of Regulatory Authority Dr. Mangali NCCP	
	Team C (Diagnosis and Treatment) Meeting among international experts of the imPACT mission, Teams of Provincial / Regional Hospitals and members of Professional Colleges related to Cancer Diagnosis/Treatment.		Venue –Galle Face Hotel

8.45 to 9.00	Registration		
9.00 to 9.15	Welcome Address and introduction of the event Dr. Janaki Vidanapatiranav Director, NCCP	Dr Asanga & Oral Health Team	
9.15 to 9.30 9.30 to 10.15	<b>Overview of distribution of cancer diagnosis and treatment facilities in</b> <b>Sri Lanka</b> Dr. Suraj Perera NCCP		
6 minutes per hospital 15 minutes kept in reserve	<b>Presentations by Provincial Hospitals:</b> TH Anuradhapura, TH Batticaloa, TH Jaffna & BH Thellippalai, PGH Badulla, TH Ratnapura		
10.15 to 10.30	Morning Tea		
10.30 to 12.15 6 minutes per hospital 20 minutes kept in reserve	<b>Presentations by Regional Hospitals:</b> NCTH Ragama, DGH Gampaha, BH Awissawella, DGH Kalutara, DGH Chilaw, DGH Kegalle, DGH Nuwaraeliya, DGH Monaragala, DGH Hambanthota, DGH, Polonnaruwa, DGH Ampara, DGH Trincomalee, DGH Vavuniya, KDU TH Cancer Centre		
12. 15 to 13.00	Lunch		

13.00 to 13.50	Discussion based on the presentations made between international experts, teams from provincial / regional hospitals and members of professional colleges.		
	Vote of thanks		
13.50 to 14.00	Dr. Priyantna wijesingne Deputy Director, National Cancer Control Programme		
09.00 - 2.00	Team A Cancer control planning		
09.00 to 10.00	Meeting with Bio Medical Engineering Division of Ministry of Health (high end equipment)		
10.15 to 11.00	Meeting with Director & D/Director (Dr Sudarshana) Medical Supplies Division (Supplies and drugs)	Dr Priyantha/Dr Nadeeja	Venue: Site visits
11.00 to 12.00	Meeting with CEO (Dr Kamal Jayasinghe) National Medicinal Regulatory Authority (NMRA)		
09.00 - 2.00	Team B (Prevention and early detection)	Dr Saddharama	
8.30	Departure from Hotel	Dr Kalpani /Dr Thanuja	Venue: Site visits
9.00 to 10.45	Meeting with NATA, ADIC & CCT @ NATA office Sethsiripaya Battaramulla		
11.15 to 11.45 12.00	Family practitioner Visit to University of Colombo Family Medicine Centre		
09.00 to 10.00	<b>Team D</b> (Palliative care) Visit to Faculty of Medicine, Department of Medical Education University of Colombo		Venue: Site visits

10.0 to 11.00	Post Basic College of Nursing		
11.00 to 12.00	Nursing Training School Colombo	Dr Sachintha/Dr Thusitha/Dr Ruchira	
12.30 to 13.00	Visit to Department of Nursing Education- University of Sri Lanka Jayawardenapura	Thushina Di Kuchina	
09.00 to 10.00	Team E (Working with Sri Lanka cancer registry team)	Dr Nirmala / Dr Chulaka Jayaweera	
10.00 to 11.00	Meetings with Head of Medical Statistics Unit MOH- Ms Dharshani		
11.30 to 12.30	Meetings with Director Information- Dr Anil Samaranayake		
	Meetings with Director (Statistic) Registrar General Department, Mr Seenadhira @ Baththaramulla Office		
14.00 - 14.30	Lunch Break – Whole team at the hotel		
15.00 - 18.00	Other experts: Report writing		Galle Face Hotel
18.00 - 23.00	Expert Team Debriefing and consolidation of findings and recommendations into summary presentation		Galle Face Hotel
	Friday 1 November (Colombo)		
9.00-10.00 10.00-11.00	Meeting regarding SL project on cyclotron for radiopharmacy (Dr. Haidar, Ms. Arias de Goebl		

11.00-11.45	Meeting with WHO WR (Ms. Arias de Goebl, Ms. Saauvaget, Mr. Veljkovikj) Meeting with Post Graduate Institute of Medicine (Sr. Haidar, Dr. Yavuz, Dr. Zujewski, Dr. Pramesh)	Dr. Janaki, Chair SLAEB, NLO, MoH Directorate for Planning	WHO Country Office
11.00-12.00			
11.00 - 12.00	Meeting with Census Bureau (Dr. Swami)		
	<b>Presentation to MoH authorities onkey findings and recommendations</b> (all national and international experts)		
12.00 - 13.30			
	Lunch and return to Hotel		
14.30 - 20.00			
15.30-16.15	Individual report finalization		
	Debriefing to UN (Ms. Arias de Goebl, Ms. Saauvaget, Mr. Veljkovikj)		
	Saturday 02 November (Colombo)		
09.00 - 16.00	Report writing and finalization (all national and international experts)		WHO Country Office

### Annex 2: Background Information on IARC, IAEA and WHO

### The International Atomic Energy Agency (IAEA) and Cancer Control

The IAEA was established in 1957 as the world's "Atoms for Peace" organization within the United Nations (UN) family. For more than 50 years, the IAEA has been working with its Member States and multiple partners worldwide to promote safe, secure and peaceful nuclear technologies, with emphasis on the use of radiation medicine and of related regulatory and safety infrastructures. Health is an important part of the IAEA's mandate and of its programmes, mainly because nuclear techniques play a major role in medicine and a particularly prominent role in fighting cancer.

The IAEA also provides advice, support and assistance with regard to all of the prerequisites to ensure radiation techniques and technologies in healthcare are used safely and securely. Focusing on capacity building and education and training in particular, the IAEA's assistance, through its technical cooperation and human health programmes, has enabled over one hundred low and middle income (LMI) Member States to establish radiotherapy services, and in many cases nuclear medicine services.

The existing radiation medicine infrastructure and available resources can cover only a small portion of the needs. Nevertheless, expanding radiotherapy capacity alone is simply not enough to control cancer. Other interventions that focus on cancer prevention and early detection are needed to increase cancer survival, reduce cancer mortality and, ultimately, make a difference. Reliable data for the planning, monitoring and evaluation of those interventions are crucial and need to be considered.

The IAEA established its Programme of Action for Cancer Therapy (PACT) in 2004 to support more effectively the fight against cancer in developing Member States, through a focus on public health. PACT stands as the IAEA's umbrella programme for coordinating cancer-related activities and builds upon existing experience in radiation medicine technology to enable LMI Member States to introduce, expand and improve their cancer care capacity by integrating radiotherapy into comprehensive national cancer control programmes, which maximize therapeutic effectiveness, sustainability and impact. Following WHO guidelines, such programmes integrate and align activities and investments in cancer prevention, early detection, diagnosis, treatment, palliative care, and surveillance into a public health system based on available scientific evidence.

### The World Health Organization (WHO) and Cancer Control

The WHO is the international agency within the UN system responsible for health. Established in 1948, its objective is the attainment by all peoples of the highest possible level of health, based on the "Health for All" concept.

One of the missions of the WHO is to provide leadership and advice on the evidence base for international action on prevention and control of non-communicable diseases (NCDs), including cancer.

Given cancer's human and economic cost, the WHO has intensified its efforts to more effectively respond to the cancer pandemic. The World Health Assembly has passed several key resolutions to put knowledge into action concerning cancer and NCD control. One such highly significant resolution related directly to cancer, resolution WHA58.22 ("Cancer prevention and control"), was adopted by the World Health Assembly in 2005. That resolution listed a number of objectives, in particular the development of the WHO cancer control strategy at the global, regional and national levels, aimed at improving knowledge to implement effective and efficient programmes for cancer control, leading to a reduction of the cancer burden and improving quality of life for cancer patients and their families. In this context, the WHO has encouraged Member States to establish National Cancer Control Plans to respond to the cancer needs in populations by preventing, detecting early, curing and caring. Basic steps of the planning process can be consulted on the WHO's website.

In September 2011, the UN General Assembly convened for the High-Level Meeting on the Prevention and Control and Non-communicable Diseases, a significant milestone in the efforts to make international commitments that put NCDs high on the development agenda. In May 2013, the World Health Assembly endorsed the WHO's Global Action Plan for the Prevention and Control of Non-communicable Diseases 2013–2020, and adopted a global monitoring framework to enable global tracking of progress in preventing and controlling major NCDs, including cancer, and their key risk factors.

WHO, as the UN agency with the overarching health mandate, sets norms and standards in health planning and implementation and assists countries in developing national health plans, including on cancer control. The WHO country offices play a key role as interface to the national health authorities. The respective head of a WHO Country Office represents the WHO Director General and the Regional Director of the respective WHO regional. Important WHO partner organizations related to cancer are Union for International Cancer Control (UICC; advocacy and communication), European Society for Medical Oncology (ESMO; access to anti neoplastic medicines survey), International Network for Cancer Treatment and Research (INCTR; cancer treatment in resource constrained settings), and International Psycho-Oncology Society (IPOS; psycho social support for cancer patients).

### The International Agency for Research on Cancer (IARC) and Cancer Control

The International Agency for Research on Cancer was established in 1965 as an autonomous agency of the WHO with the aim of promoting international collaboration in cancer research. IARC's mission is to coordinate and conduct international studies on the causes of human cancer, the mechanisms of carcinogenesis, the development of evidence-based strategies for cancer prevention and control as well as education and training for cancer research.

IARC contributes directly to the planning, implementation and evaluation of national cancer control programmes by supporting the necessary expansion of quality-assured population-based cancer registries worldwide, as well as the implementation of cancer prevention and early detection activities. The *Cancer Incidence in Five Continents* series, the GLOBOCAN database, and the publications/electronic resources, *Cancer Survival in Africa, Asia, the* 

*Caribbean and Central America (SurvCan)*, and *International Incidence of Childhood Cancer (IICC)*, produced by IARC's Section of Cancer Information, are international reference sources of incidence, prevalence, mortality and survival data.

Through the Global Initiative for Cancer Registry Development in Low- and Middle-Income Countries (GICR), IARC seeks to increase the quality, coverage and usage of registry data in LMI countries, and advocates the central role of population-based cancer registries in planning, monitoring and evaluation of cancer control activities. IARC Regional Hubs provide support, training and research capacity building activities to registries within defined world regions. IARC contributes to cancer prevention through its research into the causes of cancer and its international evaluations of carcinogenic hazards published in the IARC Monographs. IARC also coordinates research initiatives worldwide to evaluate specific strategies for prevention and early detection of cancer. The ultimate objective of this research is to guide the development of public health policies for implementing appropriate, quality assured prevention and early detection strategies in a range of health-care settings, particularly in LMI countries.

### WHO-IAEA-IARC Joint Activities on Cancer Control

In March 2009, WHO and IAEA signed arrangements at the Director-General level to implement a Joint Programme on Cancer Control. The main purpose of this arrangement is to coordinate activities and resources to provide evidence-based and sustainable support to comprehensive cancer control programmes, particularly in LMI countries.

The joint activities currently under development by WHO, IAEA and IARC further seek to raise cancer awareness, assess cancer control needs, develop cancer control demonstration projects, and attract donors in order to establish effective new funding mechanisms beyond those currently available.

#### Annex 3: Description of imPACT reviews

The inherent complexity of the different aspects required for comprehensive cancer control and the burden of the disease make it one of the most serious threats to public health, particularly in LMI countries. To address health system challenges and effectively respond to the cancer pandemic, WHO has recommended the development of national cancer control programmes, which are defined as "public health programme[s] designed to reduce cancer incidence and mortality and improve quality of life of cancer patients, through the systematic and equitable implementation of evidence-based strategies for prevention, early detection, diagnosis, treatment and palliation, making the best use of available resources".

To develop and strengthen national cancer control programmes, a systematic assessment of the cancer burden of a country is crucial. The assessment should also identify structures, service-delivery mechanisms and cost-effective interventions (based upon the latest scientific evidence) to effectively address this burden. The approach allows healthcare authorities to plan any investments in cancer control in a balanced manner that is in line with country priorities, evidence-based strategies and existing resources. It also enables Member States to build cancer treatment capacity in a manner that is complemented by other elements of cancer control.

In view of the above, IAEA offers, through its Division of Programme of Action for Cancer Therapy, a service to its Member States called the **imPACT** ("integrated missions of PACT") **Review**. The service counts on the engagement and technical support from the IAEA Division of Human Health (NAHU), Division of Radiation, Transport and Waste Safety (NSRW), Division of Nuclear Security (NSNS); with other IAEA technical divisions as appropriate.

This service assesses a Member State's readiness to develop and implement a long-term radiation medicine infrastructure and capacity-building plan, including the relevant safety, regulatory and quality assurance requirements, within the framework of a national cancer control programme. The **imPACT Review** is carried out, upon request from the health ministry of a Member State, in consultation and close collaboration with WHO, IARC and other partners. Following an intensive desk review, data collection and research process, the **imPACT Review** expert team visits the Member State to assess its comprehensive cancer control capacity and needs. During the mission, the team examines the status of existing strategies, plans, safety practices, regulations, capacities and infrastructure related to cancer services (from prevention to palliative care, including radiation medicine and human resource development), and advises on actions to be taken on the issues reviewed.

The outcome of this assessment is the "imPACT Review Report" submitted to the Minister of Health. The report is endorsed by the participating organizations and contains detailed findings and expert recommendations. Based on the report, the health ministry is expected to develop a "Short to Medium Term Action Plan" to improve services while ensuring the most efficient use of resources in the control of cancer. The implementation of the Action Plan may also lead to the design of suitable project proposals, multidisciplinary assistance packages and identification of potential sources of funding for established priorities. This in turn will help in the planning of the country's cancer-related IAEA technical cooperation projects and the relevant Country Cooperation Strategy with the WHO.

### Annex 4: Country Specific Cancer Control Resources

### World Health Organization

Publications on Cancer [English]: http://www.who.int/cancer/publications/en/

WHO guidelines and recommendations (tools) on cancer prevention and control programmes and activities: <u>http://www.who.int/nmh/ncd-tools/en</u>

Global Atlas of Palliative Care at the End of Life, 2014

Cancer control: knowledge into action, WHO guide for effective programmes (publication in 6 modules), *Policies and managerial guidelines*, 2002

WHO collaborating centre for cancer early detection and screening in Turin/Italy: http://apps.who.int/whocc/Detail.aspx?cc\_ref=ITA-101&designation\_date1=1/5/2014& designation\_date2=27/5/2014&

### **International Agency for Research on Cancer**

CANCERMondial – access to various databases on the occurrence of cancer worldwide, including GLOBOCAN, Cancer Incidence in Five Continents (CI5), Cancer survival in Africa, Asia, the Caribbean and Central America (SurvCan): <u>http://www-dep.iarc.fr/</u>

Global Initiative for Cancer Registry Development (GICR): http://gicr.iarc.fr/

### International Atomic Energy Agency

*Radiotherapy Facilities: Master Planning and Concept Design Considerations* (2014) http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1645web-46536742.pdf

*Planning National Radiotherapy Services: A Practical Tool* (2010) http://www-pub.iaea.org/MTCD/publications/PDF/Pub1462\_web.pdf

Setting up a Radiotherapy Programme: Clinical, Medical Physics, Radiation Protection and Safety Aspects (2008) http://www-pub.iaea.org/MTCD/Publications/PDF/pub1296\_web.pdf

Human Health Campus: Resources and Learning for Health Professionals http://nucleus.iaea.org/HHW/Home/index.html

Further publications related to nuclear medicine and diagnostic imaging <a href="http://www-naweb.iaea.org/nahu/NM/publication.html">http://www-naweb.iaea.org/nahu/NM/publication.html</a>

Further publications related to applied radiation biology and radiotherapy <a href="http://www-naweb.iaea.org/nahu/ARBR/publication.html">http://www-naweb.iaea.org/nahu/ARBR/publication.html</a>

Further publications related to dosimetry and medical radiation physics <a href="http://www-naweb.iaea.org/nahu/DMRP/publication.html">http://www-naweb.iaea.org/nahu/DMRP/publication.html</a>