Integrated Missions of PACT (imPACT)

Cancer Control Capacity and Needs Assessment Report

submitted to the

Ministry of Labour, Health and Social Affairs Georgia

July-August 2014

IAEA Programme of Action for Cancer Therapy PACT

World Health Organization REGIONAL OFFICE FOR Europe

International Agency for Research on Cancer

World Health Organization

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ACRONYMS AND ABBREVIATIONS

CMS	Centre of Medical Statistics
CRC	Colorectal cancer
CT	Computed tomography
DNRS	MENRP Department for Nuclear and Radiation Safety
EPID	Electronic Portal Imaging Devices
FCTC	WHO Framework Convention on Tobacco Control
GAVI	Global Alliance for Vaccines and Immunization
GEOSTAT	National Statistics Office of Georgia
gFOBT	Guaiac Faecal Occult Blood Test
GIERS	Guidance on the Import and Export of Radioactive Sources
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HDR	High dose rate (brachytherapy)
HIV	Human immunodeficiency virus
HPS	American Health Physics Society
HPV	Human papillomavirus
HTMC	High Technology Medical Centre
IARC	International Agency for Research on Cancer
ICD-O	International Classification of Diseases for Oncology
IGRT	Imaged-guided radiotherapy
IMRT	Intensity-modulated radiotherapy
IOMP	International Organization of Medical Physicists
Linear accelerator	Linac
LDR	Low dose rate (brachytherapy)
LEEP	Loop Electrosurgical Excision Procedure
MENRP	Ministry of Environment and Natural Resources Protection
MLC	Multileaf collimator
MP	Medical physicists
MRI	Magnetic resonance imaging
NCC	Universal Medical Centre (former National Cancer Centre)
NCDs	Non-communicable diseases
NCDC	National Centre for Disease Control and Public Health
NCI	National Cancer Institute
NSC	National Screening Centre
NVS	New Vaccines Support
PACT	IAEA Programme of Action for Cancer Therapy
PBCR	Population based cancer registry
PC	Palliative care

PCR	Polymerase chain reaction analysis
PET	Positron emission tomography
PHC	Primary healthcare centres
PSA	Prostate-specific antigen
QA	Quality assurance
QC	Quality control
RASIMS	IAEA Radiation Safety Information Management System
RTT	Radiation Therapists
R&V	Record and verify system
SPECT	Single photon emission computed tomography
STEPS	WHO STEP-wise surveillance
TPS-3D	3D treatment planning system
TSA	IAEA Thematic Safety Area (radiation safety)
TSO	Technical service organizations
UNFPA	United Nations Population Fund
USAID	United States Agency for International Development
VIA	Visual inspection with acetic acid
WHO	World Health Organization

EXECUTIVE SUMMARY

In Georgia NCDs and cancer in particular are estimated to account for 93% and 14%, respectively, of total deaths (WHO, 2014). With regard to communicable diseases, the situation was at its worst in the middle of the 1990s due to lower immunization coverage and disease re-emergence. The increasing cancer burden was recognized by the national health authorities and in response the Government of Georgia prepared a *National Cancer Control Strategy 2013-2018*. The Georgian Ministry of Labour, Health and Social Affairs and the National Centre for Disease Control and Public Health expressed their intention to incorporate the imPACT mission findings, conclusions and recommendations into the *Strategy* and to develop an *Action Plan*.

Georgia has no population based cancer registry (PBCR). However, the National Centre for Disease Control and Public Health plans to establish a PBCR and trains registry staff in the application of the IARC CanReg5 software. Furthermore, Georgia conducts on-going International Classification of Diseases for Oncology (ICD-O) training for oncologists.

In Georgia 55% of men and 5% of women (recent estimates are around 15-20%) are smokers. The Government has endorsed a Tobacco Control Strategy (July 2013) and Action Plan (November 2013); nevertheless there is low taxation on tobacco products. Amendments to the five tobacco laws have been prepared and, after Government approval, will be duly submitted to the Parliament for enactment.

There is an opportunistic screening programme for breast, cervical, colorectal and prostate cancers. Current coverage for breast and cervical cancer screening is around 10-11%. There are plans for an organized population-based screening programme, initially focusing on cervical cancer in the Tbilisi and Kakheti regions. The opportunistic screening was promoted through TV advertisements, and collaboration with family physicians and medical facilities. There was no invitation letter for women, but pilot text message (SMS) invitations in Tbilisi demonstrated a good initial response. There is an indication of loss of follow up between screening, diagnosis and treatment.

Georgia has full range of cancer diagnosis and treatment services, yet there is uneven distribution of and fragmented cancer care at population level. There are no national guidelines / protocols for cancer diagnosis and treatment, nor national consensus on the international guidelines to be followed. Georgia has all three cancer treatment modalities: radiation oncology (in Tbilisi and Batumi), surgical oncology and medical oncology (at secondary and tertiary health care levels).

There is an apparent challenge in regard to health care accessibility for the rural population and in regard to affordability for patients who are not able to cover the 20% out of pocket health care costs.

There is no transparent and sustained mechanism for design, implementation and review of universal health care quality criteria for different aspects of cancer diagnosis and treatment. There are no nationally approved quality criteria or guidelines for different aspects of cancer diagnosis and treatment (e.g. specialist education and training, lifecycle health technology assessment, financing of health care services, screening, prevention and palliative care).

There is no clear assessment of the current capacity and needs for cancer diagnosis and treatment systems.

There are four operational radiotherapy units for a population of 4.4 million; the units appear to be underutilized while in some regions, such as Imereti, with a population of 700 000, there is no radiotherapy facility.

The legislative framework for radiation safety and the security of sources is provided primarily through the Law on Nuclear and Radiation Safety (Law 5912, March 2012), and the Law on Healthcare (Law 1139, 1997). Two draft laws (Transport of Radioactive Substances and Radioactive Waste and Radioactive Waste Management Facilities) await promulgation.

A national infrastructure for radiation safety has been established in Georgia, including an independent regulatory body. Despite the promulgation of a revised nuclear law in 2012 there continue to be shortcomings in the legislative framework, including the absence of a comprehensive body of law and essential regulations.

The resources of the regulatory body are limited to the extent that a full programme of regulatory oversight cannot be maintained effectively, including in particular, oversight of requirements for the radiation protection of workers and effective control of radiation safety in the health sector. There is a recognized need for improvements and plans to improve the situation are under implementation.

PRIORITY RECOMMENDATIONS

In the light of the discussions held, the following recommendations are put forth:[1]

Cancer Control Planning

1. Create a national cancer control steering committee drawn of representatives from the Ministry of Labour, Health and Social Affairs, the National Centre for Disease Control and Public Health, relevant health centres / professionals and other relevant national stakeholders. Convene regular meetings to review, monitor and evaluate the progress of the *Cancer Control Action Plan 2015-2018* and ensure coordination and communication with steering committees on NCDs and Health.

2. Ensure the cancer control steering committee has balanced, broad representation from: (i) health sector (e.g. heads of cancer centres; primary care physicians; regional cancer / general hospitals; public health and health system leaders), (ii) government (relevant line ministries; specialized agencies, e.g. national development planning; local government), (iii) civil society, and (iv) media organizations.

3. Establish and promote a multi-sectoral approach to address the national cancer burden with clear mechanisms for interagency engagement and cooperation.

4. Review and revise the *National Cancer Control Strategy 2013-2018* and *Cancer Control Action Plan 2015-2018* to align with the global mandates (Action Plan for the Prevention and Control of Non-communicable Diseases and Global Monitoring Framework) and link to the national health development and NCD plans with appropriate phased targets and budget allocations.

5. Develop a human resource plan to support the *National Cancer Control Strategy 2013-2018* and *Cancer Control Action Plan 2015-2018*.

[WHO would take the lead in responding to requests for assistance in this area.]

Cancer Registration

6. Introduce legislative amendments on cancer registration.

7. Review or establish the legal status of the population-based cancer registry.

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[1] Technical Recommendations are found in Section 3.

8. Document the registration procedures in an operations manual.

9. Prepare written guidelines to ensure comparability of data in Georgian language.

[For assistance required for recommendations within this area, please consult the International Agency for Research on Cancer – Regional Hub for Western Asia and Northern Africa, based at Izmir Cancer Registry (Turkey), which may be utilized for training and support for registry development.]

Prevention

10. Effectively implement the current Tobacco Control Strategy and 5-year Action Plan in order to support comprehensive tobacco control measures aimed to curb all forms of tobacco use and to effectively implement all aspects of FCTC to which Georgia is a signatory.

11. Reach the coverage of HepB3 dose above 95% by continuing to use the pentavalent[2] vaccine and by adapting appropriate logistical arrangements.

12. Introduce and follow strict guidelines of disinfection and sterilization procedures of medical instruments to improve the control of HCV infection.

13. Include HPV vaccination in the future plans for the national immunization programme, utilizing the GAVI route, targeting 11 year-old girls through a school-based programme, which will result in a large cohort of women at low risk for cervical cancer in the future.

14. Obtain more concrete information on the prevalence and patterns of alcohol consumption as well as an economic analysis of the direct and indirect costs of alcohol consumption. This information would be very useful for advocacy efforts.

15. Implement sustained health education on harmful effects of all forms of alcohol consumption in schools and among the general public through media campaigns.

16. Make efforts to control overweight and obesity, to promote healthy diet and physical activity in daily routine activities through sustained health education for children and the general public.

[WHO would take the lead in responding to requests for assistance in this area.]

[2] By the end of 2015 Georgia intends to introduce hexavalent vaccine.

Early Detection

17. Foster early diagnosis, by focusing on improving population and professional awareness of the early signs and symptoms of common cancers, such as breast, lung, colorectal and cervix. Empower primary care practitioners and nurses in the early recognition of people with suspected cancer signs and symptoms and strengthen the referral pathways to tertiary care institutions to ensure early clinical diagnosis and prompt and adequate treatment.

18. Ensure diagnostic, treatment and follow-up health care as a prerequisite before implementation of a screening programme.

19. In order to sustain the early detection programme the available resources should preferably be used for planning, prioritizing, feasibility testing and piloting, since a full programme (breast, cervical and colorectal cancer screening) seems difficult to achieve. Also, the target ages and intervals for cancer screening should be reconsidered based on the available resources and sustainability.

20. Consider starting with a single screening programme and once this is operational, the infrastructure and systems can be progressively expanded to include other types of cancers.

[WHO would take the lead in responding to requests for assistance in this area.]

Diagnosis and Treatment

21. Develop, implement and update national diagnosis and treatment guidelines for cancer pathway in general and for management of different tumour localizations.

22. Develop national radiotherapy and nuclear medicine plan, including education and training, and integrate in the National Cancer Control Plan.

23. Review reimbursement of different diagnostic and therapeutic health care services, based on the national guidelines, and consider additional procedures (e.g. nuclear medicine) for reimbursement as appropriate.

24. Establish contemporary multidisciplinary tumour board system at every cancer care institution. This system should apply to every cancer patient.

[WHO would take the lead in responding to requests for assistance in this area. Support for recommendations relating to radiation medicine may be provided by the IAEA and may be used as a basis for the formation of an IAEA Technical Cooperation project.]

Radiation Safety

25. The Government should consider the relative merits of revising the 2012 law and issuing two other laws on waste and transport, against the drafting and promulgation of a comprehensive law with a new body of regulations and thereafter, give clear direction to the Ministry of Environment and Natural Resources Protection, Department for Nuclear and Radiation Safety (MENRP / DNRS).

26. MENRP / DNRS should urgently revise existing and/or issue new regulations to cover the spectrum of regulated activities in Georgia.

[IAEA would take the lead in responding to requests for assistance in this area.]

Palliative Care

27. Integrate palliative care into the existing structures of the national health care system.

28. Increase the availability of opioid analgesics.

[WHO would take the lead in responding to requests for assistance in this area.]

1. THE MISSION

1.1. Purpose

In view of the increasing incidence of cancer in Georgia, the Government through the Ministry of Health, Labour and Social Affairs has demonstrated its commitment to fighting cancer. Upon a request received by the IAEA in March 2013, from the Ministry of Health, Labour and Social Affairs, the IAEA's Programme of Action for Cancer Therapy (PACT) carried out an imPACT Review mission from **7-11 July** and **4-5 August** 2014.

The mission had the following objectives:

- Carry out a comprehensive assessment of the country's cancer control capacity in the areas of cancer control planning, cancer information/registration, prevention, early detection, diagnosis and treatment, palliative care, training and civil society activities;

- Carry out a capacity and needs assessment for the effective implementation of the country's radiation medicine programme, including radiation safety infrastructure, as a component of a comprehensive National Cancer Control Programme (NCCP); and,

- Explore suitable project proposals and potential sources of funding for cancer control interventions.

1.2. Team Participants

IAEA
Mr Arsen Juric, Mission Leader and Coordinator

World Health Organization (WHO)
Ms Rusudan Klimiashvili, Head of Office, WHO Country Office Georgia (observer)

Experts
Mr Anton Ryzhov (cancer registration / information)
Nominated by International Agency for Research on Cancer (IARC)

Ms Catherine Sauvaget (prevention and early detection)
International Agency for Research on Cancer (IARC)

Mr Sergei Nazarenko (cancer diagnosis / nuclear medicine)
Nominated by IAEA

Mr Alessio Morganti (cancer treatment / radiation oncology)
Nominated by IAEA

Mr Jerzy Jarosz[3] (cancer control planning, civil society and palliative care)
Nominated by WHO Regional Office for Europe

National Centre for Disease Control and Public Health
Ms Lela Sturua, Head, Non-communicable Diseases Department

Ms Nana Mebonia, Head, Chronic Diseases Unit

Ms Nino Maglakelidze, Chief Specialist, Non-communicable Disease Department

1.3. Programme

The imPACT team held meetings with representatives from the Ministry of Environment and Natural Resources Protection (IAEA National Liaison Office), the WHO Country Office, Ministry of Labour, Health and Social Affairs, as well as health professionals in different areas of cancer control, to review current infrastructure, services and future plans. The team conducted visits to cancer centres in Tbilisi and Kutaisi and met with health professionals from the National Cancer Centre (NCC) / Universal Medical Centre, Tbilisi First Hospital / High Technology Medical Centre, University Clinic, Madichi Mammological Centre, Research Institute of Clinical Medicine (Todua centre), Iashvili Children's Central Hospital, Onco-prevention Centre, National Centre for Disease Control and Public Health, Kutaisi Oncological Dispensary, Saint Nicolas Centre of Oncology and Surgery, Tbilisi State Medical University and donor agencies USAID and UNFPA to learn about the current cancer-related projects and plans in Georgia. (See Annex 1 for the Mission Programme).

A number of meetings were conducted in parallel, as members of the team met individually with relevant stakeholders to focus on respective areas of cancer control. (See Annex 2 for the List of Persons Met).

On the last day of the mission, the team briefed two Deputy Ministers: Mr Dimitri Makhatadze and Ms Mariam Jashi on the preliminary mission findings and recommended actions.

[3] Mr Jerzy Jarosz conducted the expert assessment from 4-5 August 2014.

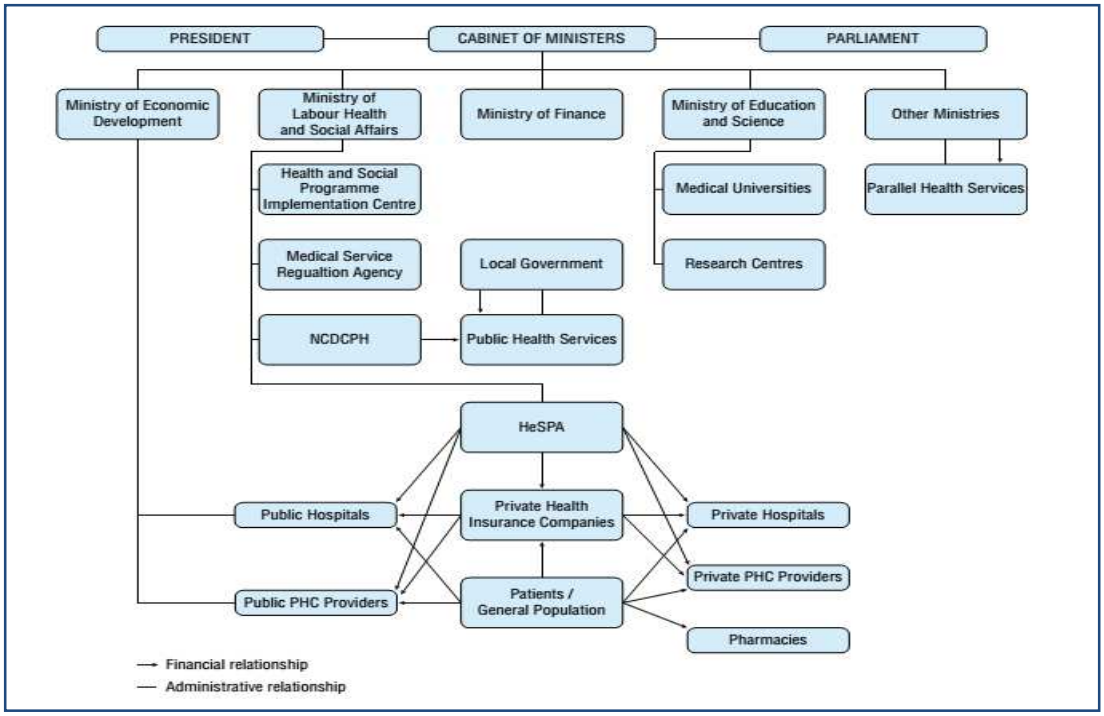
2. MISSION FINDINGS

2.1. Health System Overview

In the past twenty years the health care and health insurance systems of Georgia have undergone several structural and organizational reforms moving from a state-owned, centralized system, through privatization, to public-private partnership. These changes have significantly influenced the status and availability of diagnostic and therapeutic services. An organizational chart of the health care governance system in Georgia is presented in Figure 1.

In 1994 the Georgian health care system was transformed from the former Semaschko-model system to the Bismarck-model system. All health care institutions, including university hospitals (excluding hospitals for tuberculosis care, infectious diseases and mental illnesses), network of cancer centres (National Cancer Institute [NCI][4], regional cancer centres), all 90 oncological dispensaries, spread throughout Georgia, and producers of blood components were privatized. Some responsibilities of dispensary oncologists were taken over by family doctors[5].

Figure 1: Organizational structure of the Georgian health care system[6]



[4] In 2014 NCI was nationalized and renamed University Medical Centre.

[5] Since 2006, mandatory reporting of cancer cases was rescinded resulting in the lack of participation in the national data collection system (Source: Cancer Control Planning in Georgia, Power Point presentation, 8 July).

[6] Georgia: Health system review 2009, p.13

Despite the fact that in last two years the Georgian government has assumed more responsibility in health care governance, a decision was passed not to de-privatize the hospitals. At the same time smaller health care providers, located mainly in the rural areas will be nationalized. The current model of health care system foresees a public-private partnership between State governed financing and privately owned hospitals or State owned small scale health care providers.

The team was informed of the trend to consolidate individual private hospitals into hospital chains. For example, the hospital chain Evex Medical Corporation (formerly named My Family Clinic), which provides oncology services, has incorporated 36 hospitals located throughout Georgia.[7]

There are only few clinics capable of providing multi-disciplinary quality diagnosis and treatment. They are located in urban settings: Tbilisi, Kutaisi, and Batumi[8]. However, even in those clinics daily communication and coordination between diagnostic and therapeutic services needs to be improved.[9]

The team noted that some recent health care reforms may adversely affect proper functioning of clinical services. For instance, a private enterprise producing blood components may not be interested in supplying blood products on weekends, which may cause delays in the delivery of chemotherapeutic services at hospitals.[10]

Health Insurance and Financing

Before 2005 Georgia had a State owned health insurance scheme with funds allocated from the state budget. After 2005 a tax-based system was introduced and distribution of collected resources was managed through 5-6 private insurance companies. In 2012 the system was again changed to one where funds allocated from the state budget for health insurance purposes were distributed by the State Medical Insurance Company under a universal health coverage system. In parallel, some private insurance companies generate revenues from individual insurance contracts with Georgian health care providers.

[7] K. Kiknavalidze, West Georgian National Centre of Interventional Medicine, interviewed 9 July 2014.

[8] N. Sharikadze (MediClubGeorgia), Multidisciplinary Approach of Cancer Management, Power Point presentation, 8 July 2014.

[9] N. Sharikadze (MediClubGeorgia), Multidisciplinary Approach of Cancer Management, Power Point presentation, 8 July 2014.

[10] N. Sharikadze (MediClubGeorgia), Multidisciplinary Approach of Cancer Management, Power Point presentation, 8 July 2014.

The State governed universal health care system provides funds for basic health care services. Cancer care is partly covered under this system, e.g. a maximum of 15 000 Georgian lari (GEL, estimated US$8600) per patient is provided for surgical oncology services during the 12-month period starting from the initiation of treatment. For radiation oncology or chemotherapy services respective limits are set at 12 000 GEL (estimated US$6800). In short, the maximum State provided coverage constitutes 80% of the total costs, while the remaining 20% is out-of-pocket or private health insurance (if any) expense. An important fact is that some cancer diagnostic procedures, in particular diagnostic and therapeutic nuclear medicine procedures, are not covered by the State universal coverage scheme. This also poses a challenge in the development of diagnostic methods required for proper cancer care.

According to the Ministry of Labour, Health and Social Affairs, a survey of beneficiaries demonstrated that there is an 80% satisfaction with the universal health care coverage system.[11]

Patient Information

An important factor for cancer care efficiency is informed patient consent. According to the Georgian legislation every patient has to be informed about his/her health status, yet this requirement is not fully met. In recent years, especially since the introduction of modern clinical trials, the access to information has somewhat improved; however, according to some even with the improved situation about 80% of patients have limited information about their disease, while detailed information is only provided to the relatives.[12]

Cancer Care Path

If cancer is suspected or detected, the patient may choose the institution where to be treated. The team did not identify a formal referral system or waiting lists, other than the observed waiting line at the reception area of visited health care institutions. In most of the visited institutions the care path begins with an outpatient clinic consultation with a doctor who prescribes, and sometimes performs initial tests and then refers the patient to a specialist.

[11] Interview with Mr Dmitri Makhtadze, First Deputy Minister, Ministry of Labour, Health and Social Affairs, 11 July 2014.

[12] I. Abesadze, Universal Medical Center, National Association for Palliative Care, Cancer Prevention Center, interview on 8 July 2014.

In short, Georgia has an apparent fragmented cancer care path. There seems to be a lack of communication and coordination between the different levels of health care and between different specialists within the same health care institution. Furthermore, there was no indication of a functioning multi-disciplinary tumour board system.

2.2. Burden of Disease

The current cancer patterns in Georgia indicate that a significant proportion of cancer cases and deaths are preventable if appropriate actions are undertaken. The ageing population of Georgia will contribute to further rises in cancer burden unless structured prevention, early detection and treatment interventions are optimally scaled up in a balanced manner across the country. The estimates from the International Agency for Research on Cancer (IARC) indicate 12 361 new cancer cases (6235 among men and 6126 in women) per annum in 2012. The most frequent cancers were as follows: breast (n=1541), lung (n=1129), head and neck (n=781), stomach (n=711), colorectal (n=605), prostate (n=570), liver (n=439), corpus uteri (n=432), cervix uteri (n=425), and bladder (n=331). The estimated number of deaths from cancer in 2012 was 7319; with 3996 among men and 3323 among women.

Of the more common cancers in Georgia, lung, head and neck, cervix, stomach and liver cancers are eminently preventable, whereas control of breast and colorectal cancers predominantly relies on early detection and appropriate treatment.

Cancer incidence among top five cancer sites
(Source: GLOBOCAN 2012)

Cancer incidence					**Total number of new cancer cases/year: 12 361**				
Males					**Females**				
Cancer site	Number of cases	% of cancers	Crude rate	ASR	Cancer site	Number of cases	% of cancers	Crude rate	ASR
Lung	931	14.9	45.9	30.8	Breast	1541	25.1	67.7	44
Prostate	570	9.1	28.1	18.6	Corpus uteri	432	7.1	19	14.2
Stomach	406	6.5	20.0	13.2	Cervix uteri	425	6.9	18.7	14.2
Larynx	389	6.2	19.2	12.5	Brain, nervous system	323	5.3	14.2	6.8
Colorectum	305	4.8	15.1	9.9	Stomach	305	5	13.4	7
Total	6235	100	307.7	207.8	Total	6126	100	268.9	163.7

*ASR: Age Standardized Rate using World population; ** excluding non-melanoma skin cancer

Cancer mortality among top five cancer sites
(Source: GLOBOCAN 2012)

Cancer mortality					**Total number of cancer deaths/year: 7 319**				
Males					**Females**				
Cancer site	Number of cases	% of cancers	Crude rate	ASR	Cancer site	Number of cases	% of cancers	Crude rate	ASR
Lung	834	20.8	41.2	27.2	Breast	530	16	23.3	13.2
Stomach	340	8.5	16.8	10.6	Stomach	257	7.7	11.3	5.4
Prostate	278	7	13.7	7.6	Cervix uteri	200	6	8.8	5.7
Liver	239	6	11.8	7.9	Brain, nervous system	184	5.5	8.1	3.5
Colorectum	177	4.2	8.7	5.5	Liver	182	5.4	8	3.5
Total	3996	100	197.2	127.4	Total	3323	100	145.9	77.2

*ASR: Age Standardized Rate using World population; ** excluding non-melanoma skin cancer

2.3. Cancer Registration

Cancer control planning without reliable population data from cancer registries is prone to misplaced emphasis and wasted investment. The PBCR primary functions are collection, storage and analysis of information on cancer cases occurring in a defined population. Information on incidence and characteristics of specific cancers in various segments of a defined population and on temporal variations in incidence is the primary resource for planning and evaluation of health services for the prevention, diagnosis and treatment. PBCR can record information from multiple sources such as public and private hospitals, municipal records and other sources where cancer patients within the catchment population access services for diagnosis and treatment.

In Georgia, the state cancer registration system, established in 1995, has the following features:

- network of specialized hospitals in Georgia aligned with administrative divisions (regional oncological dispensaries);
- passive collection by departments of statistics within dispensaries of information on new cancer cases and/or information on treatment of cancer cases from any medical source;
- active follow-up on cancer cases; and,

- mandatory regular visits of patients to regional oncological dispensary near patient's residence.

In fact, this was a paper-based cancer registry; its electronic version was in operation from mid-1990s to 2007. Since 1991 major health care system changes, e.g. privatization, introduction of primary, secondary and tertiary levels of health care, implementation of health insurance system, adversely affected the development of the PBCR. The aggregated reports on cancer incidence, mortality, treatment and prevalence (Form IV-08), submitted annually by over 80 medical institutions to the Department of Medical Statistics at the NCDC (former Centre of Medical Statistics, CMS), the main source of information on the cancer burden in Georgia. The completeness and accuracy of the information in these reports are largely uncertain; therefore the burden and cancer profile in Georgia are mostly estimated. In GLOBOCAN 2012 cancer incidence in Georgia was estimated from medium quality complete national mortality estimates using modelled survival.

A population-based cancer registry needs to be established and plans should be put in place immediately, in order to establish quality data on the cancer burden and trends in the country to inform health care decision-making and resource allocation,

The need to develop a PBCR is acknowledged by the Ministry of Labour, Health and Social Affairs and the National Centre for Disease Control and Public Health (NCDC), as stated in the draft *National Cancer Control Strategy*. Preliminary actions were taken in 2011-2013 under the State Programme, including:

- translation and publishing of ICD-O-3;
- translation of CanReg5 software and training of registrars;
- translation and filling of dictionaries: topography, morphology, administrative units, and institutions providing oncology services;
- participation in international training and courses organized by International Agency for Research on Cancer (IARC);
- introduction of "Cancer notification form" on all cases diagnosed and/or treated in Georgia.

There are on-going training events on ICD-O coding for oncologists and pathologists.

In the assessment of the cancer surveillance capacity and needs the team visited medical records departments at the National Cancer Centre (NCC) / Universal Medical Centre, Tbilisi First Hospital / High Technology Medical Centre (HTMC) as well as Primary Healthcare Centres (PHCs) in Tbilisi and Mtskheta. Each facility has its own hospital information system and diagnoses are captured in ICD-10, but the scope of information stored varies between facilities. All systems capture a national patient ID.

The NCC operates a hospital-based cancer registry capturing information from patient medical records. Data management, analysis and compilations of the reports are undertaken by a team within the statistics department. The NCC team is largely involved in the cancer registration project under the State Programme with financial support from the NCDC. The NCC team conducts on-going trainings on ICD-O coding and CanReg5 application at different institutions across the country.

All institutions (NCC, HTMC and PHCs) store well-kept paper-based clinical records and staff members prepare annual state official report (Form #IV-08). Medical records are the primary source for completing the report. There is no evidence of information sharing between institutions (e.g. checking whether a case is new or duplicate or prevalent case, etc.), thus indicating concerns of over-reporting information on cancer burden in summary reports to the Department of Medical Statistics.

It is also noteworthy to highlight that the National Statistics Office of Georgia (GEOSTAT) has no information on the population size for Abkhazia and South Ossetia.

2.4. Cancer Control Planning

Georgia has a *National Cancer Control Strategy 2013-2018*. The Georgian Ministry of Labour, Health and Social Affairs and the National Centre for Disease Control and Public Health expressed their intention to incorporate the imPACT mission findings, conclusions and recommendations into the *Cancer Control Action Plan 2015-2018*.

2.5. Prevention

The current status of various cancer prevention initiatives, with brief background information and recommendations to further improve cancer prevention initiatives, are described in the following section.

Goal 2 of the National Cancer Control Action Plan aims to reduce cancer risks linked to unhealthy lifestyle. The national NCD strategies and action plans address risks related to tobacco, alcohol, unhealthy diet, obesity, and activities for health promotion, etc. There are several plans, such as curriculum on diet in pilot schools, documents on healthy diet, awareness campaigns and ban of alcohol advertising, which are not yet in place.

Tobacco control

Georgia became a signatory to the WHO Framework Convention on Tobacco Control (FCTC) in 2004 and ratified it on 14 February 2006. Georgia developed a strategy and action plan against tobacco, which is yet to be implemented.

A smoking ban already exists in many public and work places and smoking is prohibited in restaurants and hotels, but, unfortunately, the population rarely adheres. The most common form of tobacco use in Georgia is cigarette smoking. Exposure to second-hand smoke seems high in both, public and private buildings.. Electronic cigarettes are available on the market in Georgia without any regulation, while betel-quid and pan-masala are not used. Currently, warning texts cover 30% of cigarette packs and there is no pictorial warning. Excise taxes represent 30% of the retail price, which should increase annually, according to the new action plan. Tobacco advertising is banned on the radio and television, but not on the streets.

Georgia has no clinic specialised in smoking cessation. Nicotine substitution is not widely available on the market. Smoking cessation treatment is expensive and not covered by the Ministry of Labour, Health and Social Affairs, and there are no governmental funds allocated for smoking cessation activities.

Tobacco control activities are implemented by governmental and non-governmental organizations. Training of primary health care practitioners is in place. So far, there is no monitoring system to measure the impact of anti-tobacco measures, but Georgia has plans to implement such a system.

A national survey of non-communicable disease risk factors carried out between August and December 2010, using WHO step-wise surveillance (STEPS) approach, indicated that tobacco consumption is high among men in Georgia, but tobacco use is likely to be under-reported for women. The survey targeted a sampling framework of randomly selected 6839 men and women (aged 18-64 years old); 95% of target subjects participated in the survey (n=6497). The results for tobacco use frequencies (Table 1) indicate that tobacco consumption among adults remain high even five years after the signing of the Tobacco Control Act of 2006. It is estimated that there are 1.3 million smokers based on the frequencies observed in the STEPS survey.

Table 1: Prevalence of tobacco use in Georgia (STEPS survey 2010)

Tobacco use	**Total (n=6497)**	**Men**	**Women**
Current smoker	30.3%	55.5%	4.8%
Current daily smoker	27.7%	51.1%	4.0%
Among the daily smokers:			
Average age at initiation	18.6	18.3	23.2
Manufactured cigarettes (%)	98.8	98.8	100.0
Mean number of daily cigarette	19.5	20.0	14.0

Alcohol control

Georgia is among the oldest wine producing countries in the world, and the reported prevalence of alcohol drinking among adults is high, especially in men. The STEPS survey revealed that 59.4% of men and 23.4% of women above the age of 18 years were current drinkers, and that 49.8% of men and 10.3% of women had heavy episodic drinking in the past 30 days. It is important to take steps to prevent and reduce alcohol consumption in Georgia. No national strategy or concrete actions exist.

Prevention and control of Hepatitis B virus (HBV) and Hepatitis C virus (HCV) infection

Liver cancer, a highly fatal cancer, is estimated to be the seventh most common cancer in Georgia, accounting for 4% of all cancer cases. It is caused by chronic infection with HBV and HCV and the risk is further increased by alcohol consumption. Universal infant immunisation with hepatitis B vaccine is the most effective means for prevention of HBV infection and its complications, including liver cancer and cirrhosis. In 1991, in an attempt to reduce the global impact of HBV infection, WHO recommended that hepatitis B vaccination be integrated into national immunization programmes in all countries. One of the prerequisites for achieving hepatitis B control is to interrupt mother-to-child transmission by giving a birth dose. People who are first infected with hepatitis B as infants are much more likely to become chronic carriers, and chronic carriers are at much higher risk of liver disease later in life, including from liver cancer. The key strategy for preventing HBV infection is universal infant immunization with four doses of hepatitis B vaccine, with the first dose, referred to as the birth dose, being given preferably within 24 hours of birth (or at least within three to seven days from birth), since vaccination soon after birth can drastically reduce chronic carriage, followed by three more doses at 6, 10 and 14 weeks after birth.

HBV and HCV are endemic in Georgia. In a prevalence study among about 5000 blood donors, based on data from 1998, a 6.9% prevalence of HCV infection was found. Detection of hepatitis B surface antigen (HBsAg) showed that the prevalence of hepatitis B was 3.4% indicating that Georgia can be categorized as intermediate endemic zone for HBV. This study showed a higher prevalence of HCV infection, clearly indicating the need for both HBV vaccination, and strict guidelines on disinfection and sterilization (Butsashvili, 2001).

Hepatitis B vaccine coverage was introduced in 2001. From 2002, with the approval of the Global Alliance for Vaccines and Immunization (GAVI), the country received supplies of hepatitis B vaccine. Since 2010 all vaccines are procured by the government alone[13]. The birth dose is monovalent HBV vaccine and the subsequent HBV vaccine

[13] World Health Organization, Health Systems in Transition. 2009, No. 8. Vol. 11, accessible at http://www.euro.who.int/__data/assets/pdf_file/0003/85530/E93714.pdf

doses are pentavalent vaccine (diphtheria, tetanus, pertussis, *Haemophilus influenzae* type b, HBV), administered to infants during their second, third and fourth months[14]. While coverage with the three doses of hepatitis B vaccine serves as the intermediate process indicator, documented reductions in the HBsAg sero-prevalence rate will link the outcome to coverage and the quality of the immunization services. In 2013, the coverage for the third dose hepatitis B vaccination (HepB3 dose) was 93%.[15]

Prevention of HPV infection and cervical cancer by HPV vaccination

As per the GLOBOCAN 2012 estimates, Georgia has a relatively high burden of cervical cancer with more than half of its patients diagnosed at locally advanced stages. Cervical cancer is caused by persistent infection with one of the 15 oncogenic types of HPV and can be prevented by screening (with Pap smear, HPV testing or visual inspection with acetic acid [VIA]) and by HPV vaccination. It has been well established that the currently available HPV vaccines are safe and prevent persistent infection and high-grade cervical precursor lesions caused by vaccine-included HPV types (HPV 16 and 18) and may offer some degree of cross-protection. A prevalence study of high-risk HPV infection among 1309 women aged 18-50 years old and 91 locally diagnosed invasive cervical cancers was initiated in 2007. Among those with both normal and abnormal cytology, HPV prevalence was 13.5%. HPV16 was found in 58.2% of women with invasive cervical cancer, followed by HPV 45 and 18, 13.2% and 11%, respectively (Alibegashvili, 2011). Population-based HPV vaccination primarily targeting a single age-group (eg, 12 years old) among girls aged 11-13 years with high coverage can substantially reduce cervical cancer burden in Georgia since HPV16 and 18 cause around 70% of cervical cancers.

A one-year project for HPV vaccination started in July 2010. It was aimed to cover 6400 girls in the 11-13 year-old age group. The quadrivalent vaccine was provided free of charge. Vaccination was carried out in the vaccination network offices. HPV vaccine is available in Georgia at the cost of US$380 for 3 doses (Rogovskaya, 2013), but is not currently part of the national immunization programme. It seems there is no plan to implement HPV vaccination in Georgia.

In November 2011, the GAVI Alliance offered support for HPV and rubella vaccines to participating countries. Both of these vaccines were first made available to GAVI-eligible countries in April 2012 when an application round was opened for New Vaccines Support (NVS). Another round was opened in June 2013 and to support countries in preparing applications, the NVS application guidelines include information on the overall and HPV-specific application requirements. Currently Georgia has no plans to introduce HPV vaccination in the national immunization programme. As a GAVI-eligible country that has demonstrated the ability to deliver a multi-dose series of vaccines (e.g. DTP3-Hib-HepB3) to about 90% of target vaccination cohorts in urban and rural districts, Georgia

[14] UNICEF, Immunization summary, 2012. accessible at http://www.childinfo.org/files/immunization_summary_en.pdf
[15] Data extracted from http://www.who.int/immunization/monitoring_surveillance/data/en/

may seek support from GAVI to introduce HPV vaccination of 11 year-old (or 10-12 year old) girls as part of national immunization programme in a phased manner.

2.6. Early Detection

Among the major cancers in Georgia, cervical, breast and colorectal cancers are amenable for early detection. Currently, more than half of breast and cervical cancer cases are diagnosed at advanced stages even with the on-going national population-based screening programme.

The National Cancer Screening Programme was launched in 2008 with support from the National Reproductive Health Council and cofounded by the Municipality of Tbilisi and UNFPA Georgia. Under this programme, the National Screening Centre (NSC) was established with responsibility for launching and operating cancer screening programmes within the municipality of Tbilisi (breast and cervical screening in 2008; colorectal and prostate screening in 2010). In 2011, the Georgian government decided to expand all four screening programmes to the rest of Georgia with administrative control assigned to the NCDC and technical coordination to the NSC.

The screening is provided with external quality control of the cytology diagnosis and is designed on an opportunistic basis with elements of a call-recall system. Participants to the screening programme are self-reported, or symptomatic with referral from sub-contracting/collaborative primary health care centres (PHC) or general practitioners. Subjects in the target age group receive screening free of charge. In the 2 PHCs and the national screening centre, a high follow-up rate of subjects referred to tertiary hospitals for treatment was reported; most of the patients come back for follow-up visits and information on treatment completion appears to be available. PHC staff does not appear to be actively involved in creating population awareness on cancer signs and symptoms, although they are well placed to influence screening attendance and follow-up compliance. No screening activity is performed in PHC; all symptomatic persons are referred to the contractual partners of the National Screening Centre for diagnosis. The two PHCs visited were equipped with gynaecologic couches and in one centre colposcopy and cryotherapy was available; the number of Pap tests and cryotherapy procedures performed were limited (the team could not get the exact number of colposcopy and cryotherapy per month; but the centre only sees 10 women a day for antenatal care and pathology).

In Tbilisi and in some regions, cancer early detection services are provided by various medical facilities, including primary care centres, women's consultations sites, hospitals and diagnostic centres. In 2012, 23 medical facilities in Georgia and 14 medical facilities in Tbilisi were participating in early detection programmes. In addition, there are two mammomobiles that were participating in screening examinations.

The National Screening Centre in Tbilisi registers and monitors patients; however, there is no general database on the target population. Information on the target population is needed in order to properly plan, invite, and monitor the programme. Screening coverage rates are low with disparities across the country. In 2012, in the regions of Georgia, breast cancer screening coverage rate was 7.6%, cervical cancer 11.4%, colorectal cancer 0.7% and prostate cancer by PSA 1.8%. The confirmation rate among those screened positive was low and coverage rate information for Tbilisi was not available. In 2009, 16% of the target population participated in breast cancer screening and 19.5% participated in cervical cancer screening[16].

In 2013, the budget for all screening activities[17] was 2.2 million GEL (US$1 264 000); 1.1 million for regional screening project (covered by government) and additional 1.1 million for Tbilisi screening project (covered by the Tbilisi Municipality).

Georgia plans to conduct an organized cancer screening pilot project by the end of 2014 in one district in Tbilisi and in one region[18]. This project will be further scaled nationwide.

Early detection of breast cancer

Breast cancer is the most common cancer among women in Georgia. More than half of the women with breast cancer are diagnosed at stage III or IV. Target population of women are invited through TV programmes to have breast examinations at the National Screening Centre and collaborating centres. However, there is a low awareness on breast cancer among both the general population and the health care providers. PHC staff seem not to be actively involved in awareness building. The national screening programme targets women aged 40 to 70 years with mammography screening every 2 years. If mammography is positive, echography (US) and guided fine needle aspiration cytology are performed. In 2012, in the regions, except for Tbilisi, among a target population of 841 500 women, 31889 had a mammography (7.6% participation rate).

Early detection of cervical cancer

A cytology-based cervical cancer early detection programme has been on-going in Georgia since 2008[19], supported by the Ministry of Labour, Health and Social Affairs and the United Nations Population Fund (UNFPA). This programme is coordinated by the

[16] Source: http://en.calameo.com/read/000713529c700ed38547d.

[17] Includes breast clinical examination, mammography, ultrasonography, Pap test, colposcopy, biopsy, gFOBT, colonoscopy, biopsy and PSA.

[18] Yet to be identified.

[19] During the 2008-2010 it was implemented in Tbilisi, and since 2011 scaled up country-wide.

NCDC and operated by the National Screening Centre. Women are mostly referred from PHCs or by general practitioners for suspicion of cervical cancer; some are self-referred or are called back. Target age group is 25-60 years, with a screening frequency of 3 years. The centre performs about 50 Pap smears per day. Inadequate Pap smears represented 4.9% in 2012. Cytology results are obtained after 7-10 days and, if abnormal, the woman is called back for colposcopy triage and biopsy. All cervical precancerous lesions are treated by LEEP (Loop Electrosurgical Excision Procedure), regardless of grade. PHC have limited activities on cervical cancer screening providing Pap smear but not all are equipped with a colposcope for triage. One PHC was equipped with cryotherapy, with a small/handy gas tank to treat 7 women (no information if they perform single or double-freeze). There is no challenge to obtain gas refills.

Early detection of colorectal cancer

Colorectal cancer (CRC) is estimated to be the fifth most common cancer in Georgia with 605 cases per year. CRC screening is included in the national programme. It is performed by guaiac Faecal Occult Blood Test (gFOBT) at the screening centre and appropriate facilities. If the test is positive, the person is referred for colonoscopy at a tertiary hospital. The target age is 50 to 70 years and the test frequency is every year. The participation rate is very low. In 2012, in the Georgian regions, excluding Tbilisi, among a target population of 924 000, 6 565 men and women had a gFOBT (participation rate of 0.7%). Currently the number of endoscopists and colonoscopists is limited, especially in rural regions, and these health care providers are not trained in screening endoscopy. Appropriate instruction and training will need to be undertaken, together with training for endoscopy registered nurses, and endoscopy centre managers.

Hera Health Centre

This Health Centre provides full scale service in primary care and reproductive medicine on out-patient basis, including mammography screening[20]. The Centre uses quality dedicated mammographic films and automated film processors.

On a daily basis around 15 mammograms are performed, and usual detection rate of suspected cases is 15-20%; samples for cytological or morphological examinations are taken in the same centre. On average around five breast cancers are detected monthly.

The screening staff was trained in Atlanta, USA, and at Georgian and Ukrainian cancer screening centres. The Centre has two mammologists, both licensed in oncology with additional breast cancer screening training.

[20] The mammography unit was donated by the United States Agency for International Development (USAID).

The team observed that the screening films are kept at the health centre and not given to the patients even if the cancer is detected and the patient is referred for treatment to hospital (unless the patient makes a strong request). The films are kept to recover financial costs for the cancer screening programme. The team recommends a review of this practice as this causes repeated diagnostic mammograms and reduces the possibility for dynamic observation. It was reported that the diagnostic images are needed as 'financial documents'; if this is the case a hard copy can be made, and the original film should be provided to the patient to facilitate her follow-up care.

2.7. Diagnosis and Treatment

The Ministry of Labour, Health and Social Affairs acknowledges the priority need for cancer care standardization and quality improvement, which will require technical guidance and support from relevant international organizations.[21]

The expert team learned during the visits that health care institutions and departments refer to various international guidelines, sometimes a combination of different guidelines. There are no cancer management guidelines approved at national or institutional levels. In response to the call from the previous Government to develop national guidelines, professional medical societies produced over 600 clinical guidelines, 133 of which were assessed as documents of acceptable quality[22]. According to the Ministry evaluation, scientific evidence in most of the guidelines was weak and eminence-based statements prevail. The Ministry has initiated the drafting of new guidelines which will be presented for review to the medical societies.

The cost of diagnostic and therapeutic services seems to be the major barrier to effective cancer therapies in Georgia. The reluctance of patients to consult medical professionals and seek diagnostic tests contributes to the late diagnosis of cancer. In addition, even though the universal health insurance covers 80% of treatment costs the overall high costs of treatment limits the ability of patients to receive full and appropriate therapies. For example, in the case of radiation therapy many patients prefer to receive treatment at the National Cancer Centre where costs of treatment with cobalt-60 units are significantly lower compared to the treatment with a linac elsewhere. As a result, many potential candidates for curative treatment, for example for complex anatomical sites (such as head and neck), do not receive optimal radiotherapy services.

Diagnosis

[21] Meeting with the First Deputy Minister Dmitri Makhtadze, Ministry of Labour, Health and Social Affairs, 11 July 2014.

[22] Meeting with Deputy Minister Mariam Jashi, Ministry of Labour, Health and Social Affairs, 11 July 2014. Furthermore, according to Dr Nana Mebonia, NCDC, there are around 25 oncology-related guidelines.

Laboratory services for haematology and clinical chemistry are provided at most of the visited institutions on a basic level. Histology is mostly offered with traditional staining methods and cytology. Microbiological laboratories are not available in every institution, but exams are mostly accessible on an inter-institutional basis.

There is no legal requirement for medical laboratories to be certified, if operating at a medical institution. The institution is certified for its general health care services, but not for individual laboratories. At some laboratories external quality control (QC) is performed, but most of the visited laboratories did not have information on the potential external QC organizations. Some may have ISO certification, but there is no overview of the reference levels in the country.

Laboratory tumour markers are routinely available in most of the laboratories, however, data about country-wide standardization is lacking.[23]

There are currently 60 pathologists in Georgia. The majority are in Tbilisi and 8 are located outside of the capital (3 in Batumi, 1 in Zugdidi and 4 in Kutaisi). Of the 60 pathologists, 15 currently have full-time academic responsibilities; and 25 out of 60 are over 65 years old. There is an acute deficiency of pathologists in Georgia[24]. The reasons for the current situation are complex: outdated work conditions, no universally accepted pathology guidelines, lack of support in education, training and certification and low salaries. Another important issue is that all post-mortem dissections are performed in forensic institutes, and consequently medical students do not have access to dissections. If surgeons are developing new operating methods, they need special permission to access cadavers.[25] It is important to highlight that in some centres certain improvements have been introduced: automated tissue processing, embedding and staining methods, and immunohistochemical methods, as well as *in situ* hybridization.[26] The Evex Medical Corporation and Pathgeo Union of Pathologists are constructing a pathology referral centre with support from the Ministry of Health, Labour and Social Affairs. This centre will provide comprehensive modern pathology diagnostics, quality control development assistance and specialist education.

The expert team noted that endoscopy is one of the growing diagnostic technologies in Georgia. However, the equipment in most cases needs to be upgraded by replacing direct

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[23] N. Sharikadze, MediClubGeorgia, Multidisciplinary Approach of Cancer Management, Power Point presentation, 8 July 2014

[24] G. Burkadze, Association of Pathologists and Cytologists of Georgia, Anatomical Pathology service in Georgia, Power Point presentation, 8 July 2014.

[25] R. Beriashvili, Vice-rector of Tbilisi State Medical University, interviewed on 10 July 2014.

[26] G. Burkadze, Association of Pathologists and Cytologists of Georgia, Anatomical Pathology service in Georgia, Power Point presentation, 8 July 2014.

optical endoscopes with video endoscopes. In Georgia there are no endosonographic endoscopes, which have value in oncological evaluation of the disease progression of walls of hollow organs and beyond. The washing and sterilization techniques for endoscopic equipment need to be improved and dedicated washing and sterilization machines should be installed.

Concerning imaging techniques, the majority of Georgian health care institutions will need to be upgraded. Hospitals are equipped with conventional X ray devices and ultrasound machines. In some institutions CT scanners are present, while MRI scanners are mainly available at the major institutions.

Diagnostic nuclear medicine is present only in two health care institutions; however even there the technology needs to be upgraded. Available SPECT scanners should be upgraded to the level of SPECT/CT scanners and further expansion of PET/CT technologies should be considered. However, developing nuclear medicine technologies should be accompanied by the sufficient provision of radiopharmaceuticals in optimal spectrum and quantities.

There is no nuclear medicine specialization in Georgia, although there are 3-5 physicians performing nuclear medicine procedures.[27]

Several Georgian health care professionals emphasized that surgical oncology practice for lymphadenectomies needs to be improved.[28] In the opinion of the team one of the solutions to improve this situation can be the introduction of the Sentinel Lymph Node Detection Technique.

Treatment

Currently Georgia has six operational radiotherapy units (for distribution see Figure 1)[29]:

- one linac at the Oncology Centre of Adjara in Batumi;
- one cobalt-60 unit at the National Cancer Centre;
- two linacs capable of delivering 3D and IMRT treatment at the High Technology Centre; and,
- two linacs that deliver 3D and stereotactic treatment at the Todua Centre.

In practice, the radiotherapy department of the National Cancer Centre treats around 60% of patients with curative intent, while the High Technology Centre treats around 50% of

[27] Some were trained in Austria and the United States.

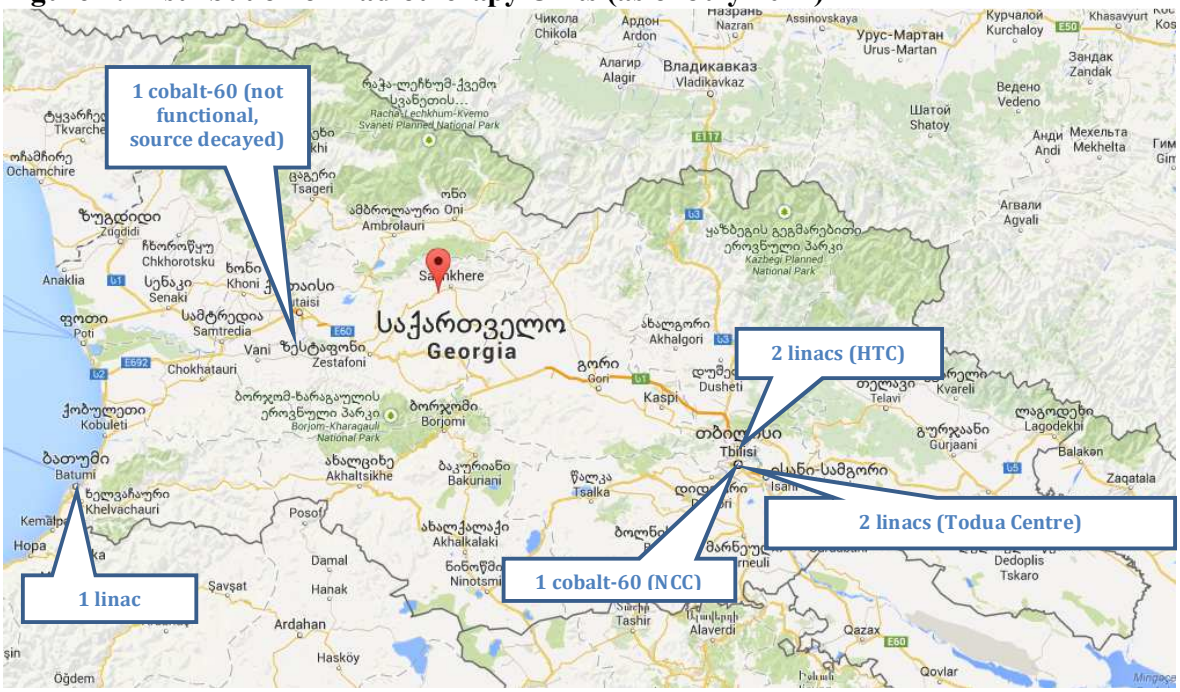
[28] High Technology Medical Centre University Clinic, Power Point presentation, 8 July 2014.

[29] Note that this information reflects the situation in July 2014.

patients with palliative intent. In the light of this situation it is advisable to consider the following reorganization of services:

- at the National Cancer Centre treat palliative care patients with the existing cobalt-60 unit on a temporary basis until the NCC acquires more modern radiotherapy technologies;
- at the High Technology Centre treat patients who need curative treatments, especially based on 3D and IMRT techniques;
- at the Todua Centre treat patients who need curative treatments, especially based on 3D and stereotactic technique.

Figure 1: Distribution of Radiotherapy Units (as of July 2014)



Notes: HTC (High Technology Center); NCC (National Cancer Center).

Radiotherapy staff did not report any waiting lists, although considering the sub-optimal ratio of one unit per million population, the lack of waiting lists is unexpected. Furthermore, the sizeable number of late diagnosis cases and the recent introduction of screening programmes, would indicate a considerable demand for palliative radiotherapy treatments. Therefore, it is assumed that radiotherapy is an underused resource compared to international standards (especially in developed countries), and that radiotherapy treatment is being replaced by other treatment modalities. Other explanations may include:

- lack of operational radiotherapy departments in some regions (such as the northwest of Georgia with about 1.5 million population);
- lack of dissemination of cancer treatment guidelines;

- limited access, due to geography or high costs of treatment;
- referral patterns; and,
- lack of awareness of medical professionals and patients.

With regard to brachytherapy, there are two units in Georgia.

Georgia has express interest in advanced radiotherapy technologies. The city of Tbilisi expects three modern linacs and one frameless robotic radiosurgery system. This would constitute high concentration of advanced technologies in a city of 1.5 million and in a country where about 50% of the radiation treatment is for palliative care purposes. At the same time the advanced treatments are not affordable for a large segment of the population. A treatment with IMRT, for example, costs considerably more than conformal treatment.

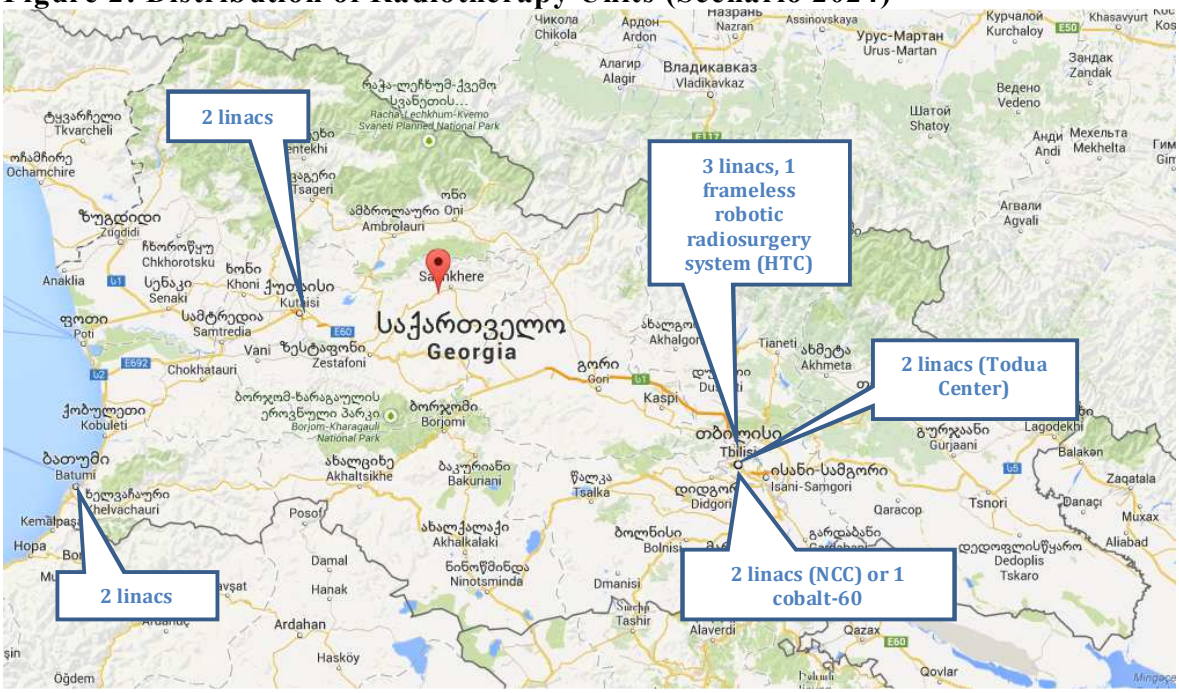
Given the number of patients treated at the National Cancer Center, it is recommended to either replace the source of the cobalt-60 unit or, if funding is available, replace the cobalt-60 unit with two linacs and the traditional simulator with a CT simulator. As long as the cobalt-60 unit is operational it is recommended mainly for palliative therapy, whereas other cases, especially those requiring 3D-CRT or IMRT such as head and neck with curative intent, should be referred to the High Technology Centre or the Todua Centre.

The centre in Batumi currently has one linac. Another linac in the same centre could increase the availability of radiotherapy treatment in the southwest region of Georgia.

In Kutaisi two linacs and an additional CT simulator should be introduced, as planned, at the Tskhakaia Centre to replace the non-operational cobalt-60 unit at the Saint Nicolas Centre. If the installation of the two linacs is prolonged (>1 year), the authorities should consider replacing the cobalt-60 source at the Saint Nicolas Center.

In the long term (>10 years) one linac should be replaced at the Batumi centre and one linac should be replaced at the High Technology Center in Tbilisi.

Figure 2: Distribution of Radiotherapy Units (Scenario 2024)



Notes: HTC (High Technology Center); NCC (National Cancer Center).

Most medical physicists, RTTs and nurses in radiotherapy departments are currently not certified. It should be noted that the IAEA provides training for radiation oncologists (main branch of general oncology) and for RTTs.

The dissemination of international cancer guidelines, adapted to the local context and resources, should be strongly considered. The use of guidelines, apparently infrequent in the visited centres, would promote quality treatments. At the same time, at least in some cases, it may reduce the burden of treatment for patients and lower therapy costs. In the case of radiotherapy, for example, none of the analysed centres employs the single 8 Gy fraction, which is internationally considered to be the standard treatment for uncomplicated bone metastases. In contrast, patients are subjected to the outdated treatment of 30 Gy in 10 fractions. Consequently, patients who could complete treatment in one day have to receive a 2-week therapy. Similarly, none of the centres employs hypofractionated (3 weeks-long) treatments for breast tumours which are currently considered to be equivalent to conventional treatments (5-6 weeks).

Closely related to the dissemination of the guidelines is the need to establish multidisciplinary tumour boards to determine appropriate therapies. During the team visits only one of the six clinical centres had an operational multi-disciplinary tumour board.

Other issues that should be addressed are the lack of quality assurance systems in patient management and lack of psychological support or rehabilitation.

Surgical oncology

Georgia has specific training for surgical oncology and surgery is mainly performed by oncology surgeons. In the visited hospitals there is reasonable availability of surgeons and operating theatres with no waiting lists. In addition, a variety of different sub-specialties of surgical oncology (breast, gastrointestinal, gynaecologic, urologic cancers and so on) are available. Paediatric surgery is mainly concentrated in the Iashvili Children's Centre of Tbilisi.

Medical oncology

The *Model List of Essential Drugs* of Georgia includes classical antineoplastic and cytostatic drugs, which are effective and used either as monotherapy or as combination therapy in contemporary chemotherapy protocols. The following drugs are missing from the above mentioned List: platinum containing drugs (cisplatin, carboplatin); ifosfamid; docetaxel; oxaliplatin; biological drugs, e.g. rituximab; trastuzumab; antidotes, e.g. uromitexani (mesna), used to reduce the nephrotoxicity of cyclophosphamide; and, antiemetic drugs, e.g. metoklopramid or ondansteronum.

Kutaisi has two centres providing chemotherapy treatment. At Saint Nicolas Centre of Oncology and Surgery there is only one medical oncologist and one nurse, while at the Tskhakaia Centre there are three medical oncologists and three oncology nurses. Centralization of chemotherapy in a single centre would improve the quality of cancer care in this town.

There is a resident training programme for medical oncologists and training courses for oncology nurses.

Georgia seems to have a national network of centres able to provide chemotherapy treatments.

The main challenges seem to be:

- high cost of drugs, 20% of costs covered by patients;
- relative unavailability of biological drugs (targeted therapies) and associated increased costs;
- lack of available spaces and security systems dedicated to the preparation of anti-cancer drugs resulting in environmental safety issues.

Universal Medical Centre (former National Cancer Centre, NCC)

This Centre provides health care services predominantly in adult surgical oncology (excluding neurosurgery), radiotherapy, chemotherapy and palliative care. In recent years it was privatized[30] and *de facto* lost its status as the national centre. The current administration recognizes the challenge and plans to strengthen the Centre services[31]. The Centre has 103 beds (70 for surgery, 15 for chemotherapy and 15 for terminal care). In the first seven months of 2014 there were 854 in-patients and the number of out-patients is unknown since ambulatory visits are counted instead.

Diagnosis

Diagnostic technologies are very limited: two ultrasound units (one portable, one stationary), two X ray machines (about 90 studies a month), endoscopy, haematological laboratory, clinical chemistry laboratory, morphology and cytology laboratory (around 30 frozen section examinations per month are performed). Blood components are purchased from a different institution, there is no modern immunochemistry, and the biological method is the sole means to match the blood groups.

Due to the absence of CT, MRI, Sentinel Node Detection Techniques, SPECT or SPECT/CT and PET or PET/CT it is difficult to properly diagnose, treat and follow-up, as well as to apply appropriate cancer care guidelines. No treatment with radioisotopes is performed.

There is an obvious need for staff training not only in the field of clinical applications but also in quality management. A quality system for all diagnostic services needs to be developed and maintained[32].

Treatment

The centre treats more than 2000 patients annually. The treatment is based on the use of clinical guidelines developed on site. There are no currently active tumour boards for the different neoplastic diseases. A system of quality assurance is being developed in the

[30] As of September 2014 the Centre again became a public cancer care institution.

[31] In 2009 IAEA/TC project GEO/6/006 'Establishment of a Nuclear Medicine Department at the Georgia National Cancer Centre' was completed.

[32] A nuclear medicine physician with solid experience developed at the prestigious Vienna General Hospital (AKH) is now providing her medical expertise in Georgia.

department of radiotherapy. A psychological unit is available to provide support to paediatric patients. The centre does not have a rehabilitation service.

There is a centre of surgical oncology, with 18 surgeons on duty, running approximately 600 interventions per year in 4 operating rooms. The centre does not have laparoscopic surgery. Surgical oncology for breast, gastrointestinal, gynaecological, urological, paediatric and other cancers are performed (no neurosurgery).

The department of medical oncology is managed by the same medical director as the department of radiotherapy. In the department of medical oncology there are 6 medical oncologists and 6 oncology nurses. The centre does not have qualified pharmacists and there is no secure system for the management of antineoplastic drugs.

The department of radiotherapy treats approximately 1500 patients per year, 40% of which are treated for palliation. A 2D technique is available, planned and performed with one conventional simulator and one cobalt-60 unit. There are no waiting times for radiation treatment. In the same department, about 400 HDR brachytherapy treatments are performed per year, using an Ir-192 source. Immobilization systems and a mould room are available. Ten radiation oncologists, three medical physicists, nine RTTs and nine oncology nurses are currently on staff. Despite the technological limitations, the centre treats all types of cancers, with both palliative and curative intent. Many cancer patients chose to be treated with a cobalt-60 unit at this centre as it is less expensive than treatment with a linac at other centres.

No treatment with radiopharmaceuticals is performed.

Considering the high number of patients treated and the fact that for financial reasons some patients may be treated only at this Centre, it would be appropriate to support the activities of this radiotherapy department.

Table 2: Treatment Equipment and Human Resources

Equipment	Years in operation	Quantity	Maintenance Contracts (Yes/No)
Simulator (Conventional)	> 10	1	No
CT simulator	N/A	0	N/A
Treatment Planning System	> 10	1 (2D)	No
Cobalt-60 units	> 10	1	No
Linac	N/A	0	N/A
Multileaf Collimator	N/A	0	N/A
Portal Imaging	N/A	0	N/A

Record and Verify	N/A	0	N/A
Brachytherapy (HDR, LDR, isotope)	N/A	1 (HDR, Ir-192)	No
Staff		**Number**	**Qualifications**
Radiation oncologists		10	N/A
Radiotherapy medical physicists (MP)		3	N/A
Radiation therapists (RTT)		9	N/A
Radiation oncology nurses		9	N/A
Repair & maintenance (biomedical engineer /technologists, r&m)		1 engineer	N/A

High Technology Medical Centre, University Clinic (HTMC)

Diagnosis

This Centre has a haematology laboratory, clinical chemistry laboratory and immunological laboratory. Morphological, cytological, microbiological and PCR studies are performed in other institutions. The laboratory participates in external quality control programmes.

The hospital has an endoscopy unit with diagnostic endoscopic devices (video endoscopes without ultrasound detectors for bronchoscopy, gastroscopy, duodenoscopy, and colposcopy) and washing machines.[33]

The Centre has four X ray devices, one angiography suite, four ultrasound machines, four CT scanners and one MRI scanner.

This Centre is one of two institutions in Georgia with a nuclear medicine department. The department has a single detector SPECT gamma camera, a PET/CT scanner and four rooms for radioiodine treatment. A Sentinel Lymph Node Detection Technique is not performed. In 2013 only 83 PET/CT scans were performed even though this is the only PET/CT scanner in the Caucasus region. Nuclear imaging techniques are underutilized which may be explained by the following:

- PET tracers are not produced in the country but imported from Turkey. The cost of FDG is high and the availability of tracers is limited due to the lack of reimbursement for nuclear medicine studies through the universal health care coverage system.
- PET/CT scanner is serviced by an Istanbul-based company, and it takes at least two working days for maintenance.

[33] Managed and owned by Professor Chavchadze.

On a weekly basis 5-6 patients with benign thyroid disease receive radioiodine treatment on an out-patient basis and 8-10 patients with thyroid cancer receive radioiodine treatment on an in-patient basis (hospital stay of 2-4 days). The patients are from Georgia and neighbouring countries. For Georgian patients the absence of reimbursement scheme for radioiodine treatment under the universal health coverage system also limits accessibility to treatment.

The nuclear medicine staff, which consists of two doctors, five nurses and one physicist, benefit from continuous training opportunities. Two physicians have received training in Georgia and in the United States; one received a one-year fellowship in Warsaw, Poland. The physicist performs both the tasks of the technologist and the radiopharmacist. There is a need for staff training in the clinical applications of nuclear medicine and quality management.

Treatment

This centre is currently reviewing treatment guidelines. There are active tumour boards for different malignancies. It is not clear whether systems for quality assurance, rehabilitation and psychological support services are available. There are about 35 surgeons, with ten operating theatres and a system of video-laparoscopy. Surgeries are performed on all body sites, and include neurosurgery, thoracic and paediatric surgery. About 35% of the surgeries are with palliative intent. There is a medical oncology service with three medical oncologists and two oncology nurses. There is a secure system for the management of antineoplastic drugs but no specialist pharmacists on the use of these drugs.

There is a radiotherapy department treating over 1000 patients per year, out of which 50% are palliative intent cases. Waiting times for radiation therapy are approximately 3-4 working days. There are modern radiotherapy techniques such as conformal radiotherapy and IMRT (the latter used for cancers of the prostate, head and neck). The treatment is planned with a CT simulator and TPS-3D, performed with two linacs with MLC, EPID and R&V system. Immobilization systems and a mould room are available.

The following brachytherapy treatments are performed: HDR technique with Ir-192 sources for gynaecological cancer and LDR technique with I-125 sources for prostate cancer.

The department has 5 radiation oncologists, 5 medical physicists, 11 RTTs and 4 oncology nurses. Two new bunkers are under construction for the installation of one additional linac and one robotic radiosurgery system.

It may be useful to consider integrated radiotherapy services between High Technology Medical Centre and the NCC; with NCC treating palliative cases and HTMC curative cases.

Table 3: Equipment and Human Resources

Equipment	**Years in operation**	**Maintenance contracts**	
Simulator (conventional)	N/A	N/A	
CT simulator	< 5	Yes	
Treatment planning system	< 5	Yes	
Cobalt-60 units	N/A	N/A	
Linacs	< 5	Yes	
Multileaf collimator	< 5	Yes	
Portal imaging	< 5	Yes	
Record and verify	< 5	Yes	
Brachytherapy (HDR, LDR, isotope)	< 5	Yes	
Staff		**Number**	**Full-time**
Radiation oncologists		5	5
Radiotherapy medical physicists (MP)		5	5
Radiation therapists (RTT)		11	11
Radiation oncology nurses		4	4
Repair & maintenance (biomedical engineer/technologists, r&m)		N/A	N/A

Note: N/A=information not available

Iashvili Children's Hospital (Tbilisi)

This is the largest paediatric hospital in Georgia with 300 beds. It is a teaching hospital belonging to the Avante Group formed by four private hospitals. Children up to the age of 18 from all over Georgia are treated at this hospital. For oncological and haematological care there are 34 beds.

This paediatric care centre has no active multi-disciplinary tumour board. The team was informed that German guidelines are followed. There is a system of quality assurance and psychological support services. There are 15 paediatric surgeons performing about 100 interventions per year for all cancer sites. There is a chemotherapy department with 5 physicians and 10 nurses trained in paediatric oncology, but no radiotherapy service or

treatment with radiopharmaceuticals. Patients who require radiotherapy are referred to the High Technology Centre.

In Georgia there are annually about 230-300 newly diagnosed paediatric cancer cases and about 30 newly diagnosed paediatric haematological cases. On average, this hospital performs 1-2 oncological surgeries every month. In addition, every week about 4-8 neurosurgeries are carried out among others for traumas, and tumours. Paediatric patients who need palliative care are referred to the National Cancer Centre.

Paediatric patients aged 0-18 years are fully covered under the universal health care system on a reimbursement basis. Close to the hospital is a dedicated Parents House where the parents can stay during the treatment. The QA department of the hospital regularly performs clinical outcome audits.

Diagnostic facilities are in place, except for nuclear medicine. For diagnostic nuclear medicine services patients are referred to the High Technology Medical Centre. For nuclear medicine therapies (e.g. in neuroblastoma) patients are referred abroad.

The hospital has haematology laboratory, clinical chemistry laboratory and microbiology laboratory. Morphological exams are obtained from nearby institutions. The hospital's strength is a well-developed diagnostic service for haematological diseases, including flow cytometry, cytogenetic, phenotyping, PCR-analysis, and other bone marrow studies.

Endoscopes, which are cleaned manually, are available for bronchoscopy, gastroscopy, thoracoscopy, and cystoscopy examinations.

The hospital has one fixed and two mobile X ray devices, manual film processing tools, but no dental radiography. There are five ultrasound devices, three predominantly for cardiac studies, two for other applications in musculoskeletal and other systems. There is also a CT scanner with 32-row detector and a 0.5T MRI scanner.

The team was informed that there is no waiting list for any diagnostic procedures.

Research Institute of Clinical Medicine (Todua Centre, Tbilisi)

This hospital demonstrated the state-of-the-art health care technologies. The hospital has approximately 25-30 beds and operates predominantly on an out-patient basis. Total number of outpatients in 2013 was 43 000, out of which 60% were cancer patients. The number of patients is increasing (25 000 during the first six months of 2014), and also the share of cancer patients is rising.

The hospital has four operating blocks (equipped with 3D laparoscopy), where 10-15 daily surgeries are carried out. There is a department for chemotherapy and a department for radiotherapy with two linacs. Additionally, the hospital has a dedicated department of clinical trials.

There is a wide spectrum of diagnostic technologies: a laboratory, covering all fields of laboratory medicine, three endoscopy units, two conventional X ray units, one mammography unit, ten ultrasound units, three CT scanners, four MRI scanners of 1.5T and 3T and two SPECT scanners. Technetium generators are procured from Turkey.

No treatment with radiopharmaceuticals is performed.

The staff report follows "European" guidelines and multi-disciplinary tumour boards are active. The Institute lacks a quality assurance system, as well as psychological and rehabilitation support services.

There are 20 surgeons who perform about 1600 operations per year in 4 operating rooms equipped with video-laparoscopy systems. Interventions are for nearly all cancer sites (no neurosurgery and no paediatric surgery). There are two medical oncologists and two oncology nurses in the medical oncology department. Secure systems are used in the preparation of antineoplastic drugs but there are no specialized personnel for the preparation of these drugs.

The radiotherapy service is in the development phase. It has two last generation linacs (TrueBeam) equipped for 3D radiotherapy, IMRT, IGRT and stereotactic radiotherapy, and equipped with MLC, R&V, EPID. Treatments are planned with CT simulator and TPS-3D. Immobilization systems are available. The department has three radiation oncologists, four medical physicists and five RTTs, but no brachytherapy service.

It is not entirely clear whether there is any continuous professional development for radiation oncologists. The head of the department has a nuclear medicine background. Furthermore, the team was informed that some palliative care patients were treated while dosimetry checks for the commissioning of the two linacs was on-going.

Table 4: Equipment and Human Resources

Equipment	Years in operation	Quantity	Maintenance contracts
Simulator (conventional)	N/A	0	N/A
CT simulator	0	1	Yes
Treatment planning system	0	3 (3D)	Yes
Cobalt-60 units	N/A	0	N/A

Linacs	0	2	Yes
Multileaf collimator	0	2	Yes
Portal imaging	0	2	Yes
Record and verify	0	1	Yes
Brachytherapy (HDR, LDR, isotope)	N/A	0	N/A
Staff		**Number**	**Qualifications**
Radiation oncologists		3	N/A
Radiotherapy medical physicists (MP)		5	N/A
Radiation therapists (RTT)		4	N/A
Radiation oncology nurses		0	N/A
Repair & maintenance (biomedical engineer/technologists, R&M)		0	N/A

St Nicolas Surgery and Oncology Center (Kutaisi, Former Oncology Center of Western Georgia)

This is an old, partially renovated hospital, especially the surgery facility. The Center does not have guidelines, multi-disciplinary tumour boards, systems of quality assurance, psychological support or rehabilitation services. There are five surgeons involved in cancer treatment working in 3 operating rooms with the availability of a video-laparoscopy system. Surgical procedures for breast, gastrointestinal, gynaecological and urological cancers are performed. There is a medical oncology service with one medical oncologist, and one oncology nurse. There are no specialist pharmacists and no secure system for the management of antineoplastic drugs.

There is a radiotherapy unit with a conventional simulator and a cobalt-60 unit with the required staff. However, the service is not functional on account of the decayed cobalt-60 source. The staff is expected to move to the Tskhakaia National Centre as soon as the radiotherapy service becomes operational there.

The decision not to replace the cobalt-60 source is not clear, especially in the light of the fact that northwest Georgia, with a catchment population of 1.5 million, requires access to radiotherapy services. The establishment of another radiotherapy department in a different hospital in the same city does not appear to be an effective and viable solution, since the construction of the bunkers has not yet begun. In addition, the radiotherapy staff is not ready (by own admission) to operate the new technology at the new centre.

No diagnostic or therapeutic nuclear medicine service is available on-site.

West Georgian National Centre of Interventional Medicine (Tskhakaia National Centre, Kutaisi)

The hospital belongs to the Evex group of private health care institutions and, in some cases, collaborates with the St Nicolas Surgery and Oncology Center, located in the same city.

Diagnosis

Diagnostic services are quite well developed, however not all modern technologies are available (see details below).

There is a haematological and clinical chemistry laboratory which carries out external quality controls on a regular basis and has ISO certification. Blood groups are evaluated with the help of Coomb's tests on cards (not in vials). Samples for microbiological testing are sent to another institution.

The hospital has three pathologists. Morphology and cytology laboratory and basic HE-staining of samples is performed. The hospital group Evex plans to establish a centralized pathology laboratory in Tbilisi, where the samples from all 36 member hospitals could be collected for diagnosis.

The team was informed that this hospital has two surgeons operating the Pentax endoscopes (bronchoscopes, gastroscopes, coloscopes), and Olympus washing machines for endoscopes. Since the team was not able to observe these medical devices, the compatibility of diagnostic devices and washing machines remains unclear.

Imaging technologies are represented by two fixed X ray devices, two C-arms, one mammography unit, several mobile X ray units, several ultrasound machines, two CT scanners with 64 and 2 row detectors, one MRI scanner of 1 Tesla. There are ten doctors reporting CT exams, four staff in MRI and 5 staff in ultrasound. For radiology, the film processing is done manually.

The hospital intends to procure nuclear medicine equipment; currently there are no facilities for diagnostic or therapeutic nuclear medicine.

There is a need for staff training programmes in diagnostic services; and the establishment of quality assurance systems should be a long-term goal.

Treatment

The hospital provides surgical oncology (excluding neurosurgery and haematology) and chemotherapy for adult patients only on an out- and in-patient basis, and haematological services on an out-patient basis. The hospital plans to add robotic surgery to its services. The hospital performs about 4000 surgical operations per year, 800 of them are oncological (of which palliative surgery covers 35%). The interventions include breast, gastrointestinal, gynaecological, urological and other cancers. No neurosurgery or paediatric surgery is performed. The department of medical oncology has three medical oncologists and three oncology nurses. There are no specialized pharmacists and/or secure systems for handling antineoplastic drugs. The medical director informed the team that the Centre will soon start with the construction of two bunkers for two linacs for the new radiotherapy department. No treatment with radiopharmaceuticals is performed.

2.8. Radiation Safety Infrastructure[34]

The imPACT Review team did not include an expert in the area of radiation safety or security of radioactive sources.

Radiation Safety Infrastructure

The last comprehensive IAEA review of the Georgian national infrastructure for safety was conducted in 2005 (RaSSIA). Since then, the country has been through considerable changes and developments that impacted the regulatory framework.

The legislative framework for radiation safety and the security of sources is provided primarily through the Law on Nuclear and Radiation Safety (Law 5912, March 2012) and the Law on Healthcare (Law 1139, 1997). Two draft laws (Transport of Radioactive Substances and Radioactive Waste and Radioactive Waste Management Facilities) await promulgation.

In March 2012, Georgia promulgated a new Nuclear and Radiation Safety Law (Law 15912) developed in consultation with the IAEA. This established the Georgian Ministry of Environment and Natural Resources Protection (MENRP) as the regulatory body, responsible for implementing state regulations for nuclear and radiation safety and within the Ministry, a Department for Nuclear and Radiation Safety (DNRS) to provide administrative control over nuclear and radiation safety, in effect the body delegated by the Ministry to perform regulatory functions. However, the Law (notably Article 9) also assigns a range of regulatory functions and responsibilities to other Georgian Ministries and organizations.

[34] The following information (taken from a recent IAEA advisory mission, high-level seminar and RASIMS profile) reflects the radiation safety infrastructure in Georgia according to the latest updates in RASIMS.

This revised law, while still not fully compatible with IAEA safety standards and guidance, significantly improves Georgia's capacity to align with international standards and thus, to implement an effective national regulatory framework for safety. Until today however, most of the regulations (specified in the new law to be promulgated in early 2015) have not yet been issued or drafted. Also, the new law is not comprehensive and separate laws remain in draft for waste management and transport of radioactive materials.

Georgia has expressed support for the IAEA 'Code of Conduct on the Safety and Security of Radioactive Sources' and the 'Supplementary Guidance on the Import and Export of Radioactive Sources', but the Government of Georgia has not yet made arrangements for the exchange of safety and security related information with neighbouring countries.

Legislation and regulations

The 2012 law is broadly compatible with the relevant IAEA General Safety Requirements. The Code of Conduct on the Safety and Security of Radioactive Sources (CoC 2004) and its associated Guidance on the Import and Export of Radioactive Sources (GIERS) have, to the extent possible, been incorporated into this law.

Regulations are drafted by DNRS, and approved internally by MENRP. In most of the cases the approval of parliament is not required. Occasionally, however, the Prime Minister's approval is needed.

The current 2012 law requires that the full set of implementing regulations will be written and adopted by January 2015. This drafting is way behind schedule due to organizational issues and government rejection of earlier drafts. As a consequence, there are serious difficulties with developing and issuing the necessary body of regulations. The law requires 16 regulations, but only to date one regulation namely the BSS (based on GSR Part-3), is in the process of adoption. Whilst this is undoubtedly the most complex and immediately essential regulation, nevertheless 15 regulations remain to be drafted. Given that DNRS did not meet the deadline of January 2015, a justification, together with a plan for delivery of a body of regulations at a later date, was provided to the Parliament.

MENRP and DNRS remain undecided on the strategy for addressing these shortcomings. The following two alternatives are under consideration: -) to propose amendments to the current law for consideration and, in parallel, propose the promulgation of laws on waste and transport, together with the issuance of all remaining 15 regulations. As regulations are not yet drafted, this first option is considered to be a short-term measure. -) the second, preferred option is to draft a comprehensive law (incorporating the draft laws for

transport and waste and any other elements that may be necessary) and develop regulations for this law in due course. This second option would still require essential amendments to the current 2012 law, but DNRS believes this would be accepted if their justification for these changes is soundly based on achieving an effective infrastructure for safety, in accordance with international best practice.

The general Law on Licensing and Permits is utilized for the purpose of issuing licences relating to facilities and activities involving ionizing radiation. In Georgia, any type of licence has to be in accordance with the provisions of this law. There is no provision in the law regarding duration, thus licences are not subject to renewal. Furthermore, a licence cannot be suspended; consequently enforcement is problematic. An amendment of the law on fees for licensing is proposed to allow for a scale of fees to be applied. The Administrative Code requires revision to enable Georgia to improve its radiation safety legislation in line with IAEA requirements and guidance.

Regulatory Body and Effective Independence

MENRP is defined in legislation as the regulatory body, with DNRS assigned as the administrative agency within the Ministry. This is not a perfect model, but in Georgia it is felt to be a workable approach within the boundaries of the Georgian system of government. This structure fits the regulatory model for Georgia and is used by other similar agencies. Consideration is being given to the designation of DNRS as the regulatory body, accountable to MENRP, when the law is revised.

To the extent possible within the Georgian system of legislation, the regulatory body is effectively independent in its decision making on safety matters, although the Government and Prime Minister can overrule MENRP and DNRS decisions. Ministerial departments must also approve some decisions of the regulator.

Staffing

Almost all staff of DNRS have dual roles, participating by rotation, in authorization, review and assessment and as inspectors of all kinds of facilities. It is understood that there are insufficient staff to implement the minimum level of the inspection programme (which is based on the number and nature of regulated facilities and activities in Georgia, but not on a graded approach according to risk).

No formal training or continuous professional development programmes have been established besides on-the-job training, or that provided through IAEA-organized training events.

National Register of Radiation Sources

MENRP, through DNRS, has established and maintains a national registry of facilities, sealed radioactive sources, radiation generators and activities. Since 2004, DNRS has been using ARIS (provided by USNRC and compatible with RAIS).

A permit system is the prime means of notification. Permits are required for any action that is not an already authorized use of a licensed source or facility (e.g. import, export, transfer etc.).

By current legislation, all used radioactive sources must be returned to country of origin. This does not appear to be happening in practice and it is not clear how this would be funded.

Unlike radioactive sources, there is no detailed requirement to notify the existence or use of an X ray generating device by law. DNRS becomes aware of generators through inspection and notifications on import. There is a penalty for failing to notify any source (assumed to include generators), but it is small and non-variable (200 Georgian Lari, estimated at less than US$100).

Authorization, Review and Assessment

Authorization by the regulatory body is a prerequisite for facilities and activities not otherwise exempted or approved by a notification process. All sources and generators, except those exempted according to legislation are subject to authorization and licensing. DNRS always performs a review and assessment of relevant information to determine whether an applicant for authorization complies with applicable safety requirements and authorization conditions.

The technical submission provided by an applicant (or an existing licensee seeking a change of licence or conditions) is usually provided by one of two licensed TSOs in the private sector. Although these TSOs are licensed, the licence is without limitation and there appears to be little or no oversight of their activities and competences.

With the promulgation of the 2012 law, pre-licensing inspection was stopped (through legislative action) on the grounds of cost and interference with the conduct of business. This is problematic because it requires that licences are issued on the basis of trust in the reliability, accuracy and integrity of technical submissions.

After review and assessment, authorization documents are prepared in accordance with Georgian administrative procedures. Following this procedure the Minister of

Environment signs and issues an administrative order. On the basis of this order, DNRS issues the licence itself (signed by the Head of DNRS). After the licence is issued the operator has to submit an annual report to demonstrate continuing compliance with the licence and its conditions. It is understood that a graded approach is used in doing so.

Whereas there is a requirement for a licence in legislation, there is no mechanism for defining the conditions associated with the licence. Thus, the licence is vague in terms of its scope relative to the facility and/or activity and it is difficult to restrict activities whilst enforcement orders are in place.

Inspection and Enforcement

DNRS performs inspections to verify that authorized parties are in compliance with regulatory requirements.

There is an inspection programme, based on the number of licensed facilities and activities in Georgia, but only one planned inspection type and procedure. There is no graded approach based on risk and no variations during the course of the programme in accordance with the facility / activity, etc. (except that the first inspection is different).

Unplanned inspections, including technical measurements, are occasionally performed, in cases where DNRS believes a significant problem is anticipated. The lack of inspectors however limits its capacity to conduct such inspections. .

After an inspection is completed a statement of the inspection is made on site and given to the licensee, who must sign it, thus accepting what is written there. If the licensee does not accept the findings, they can add their own opinion, which could be used as the basis for an appeal.

A DNRS inspector writes a report for the attention of the Minister and three letters, one for the Minister, one for the court and one to the Head of the legal department in MENRB.

Where there has been a reported non-compliance, DNRS must await the decision of the court (usually no more than a month). Whereas the regulatory body may suggest the penalty, it has no authority to take enforcement actions of any kind without the court's decision. However, exceptionally, by Article 28 of the Nuclear Law the inspector has the authority to require immediate, temporary cessation of an activity, or the closure of a facility in a situation of immediate risk.

After the court decision, the Minister signs the order for the enforcement action to be taken. If the licensee does not accept the decision of the court, an appeal to the court for a review can be submitted within 10 days.

Until 2012 there was a pre-licensing inspection. This ceased after the new law was promulgated.

To obtain a licence the operator must submit documentation to show that all occupationally exposed workers will have personal dosimeters. However, because a pre-licensing inspection is no longer conducted, DNRS has to accept this on trust. In the case of non-compliance, an enforcement process is implemented, including an order to the court, which may impose a fine, if the situation is not rectified in a specified time. MENRB issues an order to the licensee to rectify the situation and requires the licensee to inform MENRB in writing if in compliance.

Management System

There is no formal management system in place.

Conclusions for national infrastructure for radiation safety

A national infrastructure for safety has been established in Georgia, including a regulatory body for radiation safety. Despite the promulgation of a new nuclear law in 2012, there continues to be shortcomings in the legislative framework, including the absence of a comprehensive body of law and essential regulations.

Due to limit resources of the regulatory body a full programme of regulatory oversight cannot be maintained effectively.

There is recognition of the need for improvements and plans are being implemented. However, IAEA assistance and support will be required in most areas.

Occupational Radiation Protection (IAEA TSA-2)

There are limited and incomplete regulations in place concerning occupational radiation protection. Amongst these, Technical Regulation No28 (January 3, 2014) on Radiation Safety Limits (re-enforced Radiation Safety Limits 2000) identifies two groups of workers for all facilities: Type "A" personnel who work directly with ionizing radiation source and type "B" personnel who work in an environment of radiation exposure. These categories exclude emergency activities for facilities and other circumstances (there are other regulations and limits for emergency response).

Individual monitoring for external radiation sources

Facilities with Type A personnel are obliged to ensure TLD dosimetry. There are however only a few technical support provider entities (licensed companies) offering TLD measurement.

In certain circumstances (such as emergency teams, border police, customs and the reference laboratory of the Ministry of Justice) personal 'active' (digital) dosimeters and portable dose rate meters are available.

DNRS inspects dose records in regulated facilities. All licensed operators are obliged to report annually on occupational doses.

There is a SSDL in the country. The TLD system is type-tested by the manufacturer; however, there is no information on whether regular performance testing and uncertainty analysis are in place.

Only 25% of occupationally exposed workers currently receive personal external dosimetry.

There is no internal dosimetry service in Georgia.

Workplace monitoring

By law, workplace monitoring is a condition of a licence to operate a practice (Law on Nuclear and Radiation Safety, article 23). MENRP may perform initial monitoring during the licensing process, with inspections at a later stage.

Workplace monitoring may be performed by the operator or by another licensed/ authorized organization. Standard workplace monitoring procedures in radiotherapy and nuclear medicine are performed by equipment providers on a contract basis.

The SSDL laboratory is equipped to calibrate radiometers, spectrometers and contamination monitors. The SSDL issues a certificate on calibration of each device and thereby takes responsibility for proper operation of such a device.

Performance testing of installed equipment is mainly done by equipment providers on a contract basis. There are standard performance testing procedures in radiotherapy and nuclear medicine.

Workplace monitoring, although mandatory, is not provided in all practices.

Service providers

Necessary infrastructure for personal and workplace monitoring, advising and training is still in development. The infrastructure to provide an adequate background for advisory, equipment maintenance and repair services does not exist.

Implementation of the requirements by end users

A radiation protection programme is a mandatory part of documentation provided by the applicant prior to licensing (Law on Nuclear and radiation Safety, Article 17). All non-exempted practices are subject to authorization and a national radiation protection programme has been outlined in annexes to amendments to general law. However, the extent of end-users implementation of these requirements is unknown.

Radiological Protection in Medical Exposure (IAEA TSA-3)

Regulations

The 2012 Law regulates nuclear and radiation activities involving atomic energy between all entities, governmental as well as private and physical persons. It defines responsibilities of Governmental bodies from the regulatory perspective; rights and responsibilities in the licensing and inspection processes; activity connected with atomic energy use; protection of public health and the environment.

The Law on Licenses and Permits (June 24, 2005 as amended March 27, 2012) defines state policy on licensed activities. There is only one licence definition for nuclear and radiation practices. Particular types of licences (18) and permits (4) are defined in the Law on Nuclear and Radiation Safety.

The Law on Public Health adopted on June 27, 2007 assigns responsibility to the Ministry of Labour, Health and Social Affairs for the elaboration of safety norms for handling sources of ionizing radiation and for treatment and diagnosis using ionizing radiation.

The Radiation Safety Limits 2000 (RUN 2000) adopted by order of the Minister of Health and Social Affairs of Georgia, has the status of hygiene normative act and is currently the main regulation on implementation of principles described in the Law on Nuclear and Radiation Safety. The document is derived from the superseded "*International Basic Safety Standards for Protection against Ionizing Radiation and for*

the Safety of Radiation Sources" Safety Series 115. A new regulation, "*Radiation Safety Norms and Basic Requirements for Handling of Sources of Ionizing Radiation*" is anticipated to be adopted shortly by order of the Minister of Energy and Natural Resources. This new regulation is based on General Safety Requirements Part-3 (GSR Part 3).

Two other normative documents, namely; 'Orders of the Minister of Labour, Health and Social Affairs No.42/n on "*Basic Sanitary Rules of Handling of Radioactive Substances and other Sources of Ionizing Radiation*" and No.41/n on "*Sanitary Norms for Radiation Protection during Medical X ray and Radiological Procedures and Treatments*" adopted March 4, 2003 together with RUN 2000 currently covering medical radiation practices, are outdated.

DNRS is responsible for planned and unplanned inspection of medical radiation practice licences. Planned inspections are developed and confirmed yearly. The frequency of the inspection depends on the type of the facility, taking into account approved criteria for the risk assessment.

Legislation and regulations do not oblige medical organizations to hire medical physicists in a diagnostic radiology facility. At Georgian universities, there is no education and training for medical physicists.

Legislative rules require initial training and quarterly updates on radiation protection for medical and paramedical personnel. Medical radiologists should have state medical certificate, reflecting post graduate training in radiology, updated every five years. Other post-graduate residency programmes include medical radiology as a component e.g. interventional cardiology. All the above mentioned programmes include radiation protection.

There are only a few licensed organizations which provide training services on radiation protection but without specific details for radiology departments.

There are two professional societies of radiation protection experts, medical physicists and physicians in Georgia, specifically, the Georgian Medical Physicists Society which is a member of IOMP (International Organization of Medical Physicists) and Georgian Health Physics Society which is a partner of American Health Physics Society (HPS).
Private companies, which received state licences, provide technical services for X ray equipment (repairing, maintenance, assembling, installation and permanent control of technical conditions). The main suppliers of medical equipment and installations cover the warranty and maintenance and through additional contract, may continue such services.

Training on radiation protection is also provided by international partners (WHO, IAEA etc.) however not on a regular basis and the number of trained personnel is insufficient to cover the whole health sector.

The Radiation Safety Norms and Requirements establish the basis for patient dose as low as reasonably achievable (ALARA). Hospitals are obliged to implement mechanisms during medical treatment and diagnostics procedures to ensure optimization in this regard.

In accordance with legislation all clinical radiology departments should provide measurement and recording of patient dose. Currently most medical facilities equipped with digital devices have implemented an internal monitoring programme for patient dose which establishes the basis for quality control together with other indicators.

The legal document "*Radiation Safety Norms and Requirements*" establishes the basis for Guidance and reference levels for medical treatment and diagnostics
In accordance with legislation, each hospital should have person responsible for radiation safety. The responsible person is obliged to provide training on radiation protection at least twice per year for personnel of 'A' category.

In accordance with the Law on Nuclear and Radiation Safety and the Georgian Radiation Safety Norms and Requirements, each licensee is obliged to carry out annual quality control tests of X ray generators. Such tests should be implemented by technical service organizations (TSOs) licensed for such activities. Currently, only two legal entities act as TSOs in Georgia.

Clinical radiology departments are obliged, by the Radiation Safety Norms and Requirements, to implement dose reduction while maintaining diagnostic confidence for digital X ray facilities.

Georgia has approximately 24 mammography units, including one digital mammography system. There is no quality control programme for assessment of patient dose for this high risk application.

There are approximately 56 CT operational units. Specific training to educate medical professionals on the relatively high dose in CT is included in residency (post-graduate programmes) for medical radiologists only.

There are no mechanisms for radiation protection training for paramedical personnel. There are no defined training centres or formal training programmes. It is understood that Radiation Protection Professional societies train both medical and paramedical personnel.

Patient doses and image quality assessments in interventional radiology are not regularly performed.

There is no mechanism to follow up on cases of suspected high patient dose because no records are kept of examinations that could have resulted in high dose (such as fluoroscopy times longer than 30 minutes). Hence, there is no mechanism for recording and reporting radiation injuries.

Georgia has three facilities offering nuclear medicine technologies with two diagnostic and two therapeutic nuclear medicine departments.

Law No.1674-1s 1999 is not specific with regard to the licensee having to nominate a radiation protection specialist in a nuclear medicine facility. The Law only states that "*each individual working with ionizing radiation should be trained according to a prearranged programme and timetable*".

At nuclear medicine facilities there appear to be no protocols for calibration and radiation protection.

No surveys in image quality in nuclear medicine facilities were undertaken.

There are no national guidance levels for radiopharmaceutical activities.

There is no action plan in case of maladministration of a radiopharmaceutical.

There are no guidelines on release of patients undergoing radionuclide examination.

There is no information on arrangements for maintenance and servicing of nuclear medicine equipment.

The Law on Nuclear and Radiation Safety obliges the licensee to nominate a qualified medical physicist in a radiotherapy facility. Each department has at least one medical physicist.

All Georgia radiotherapy departments are licensed. In accordance with licence conditions, the licensee should report any change related to the use of radiation sources, including staff changes. Also, the hospital is obliged to record any emergency case,

including incidents and accidental exposure. All licensees are obliged to send an annual report to the DNRS.

Quality control procedures are performed by medical physicists who also provide clinical dosimetry for gamma radiotherapy equipment for all regional centres and protocols for calibration.

All radiotherapy equipment in the radiotherapy departments is serviced by private companies that provide technical services and maintenance.

Security of Radioactive Sources for Medical Applications

Georgia and the IAEA have jointly developed an Integrated Nuclear Security Support Plan (INSSP) which covers all issues related to nuclear security, including the security of high activity radioactive sources for medical applications. The INSSP was discussed and finalized through a meeting in Tbilisi, Georgia, in February 2014. The lead government agency for Georgia's INSSP is the Nuclear and Radiation Safety Department, Ministry of Environment and Natural Resources Protection, and the Point of Contact is Ms Lia Chelidze.

The legislative framework for the safety and the security of sources is provided primarily through the Law on Nuclear and Radiation Safety (Law 5912) of March 2012 and the Law on Healthcare (Law 1139) of 1997. The Georgian Ministry of Environment and Natural Resources Protection (MENRP) through the Department for Nuclear and Radiation Safety (DNRS), is performing regulatory functions in Georgia. However, it requires additional powers to fully carry out nuclear security responsibilities, which will be addressed in the new revision of the law in 2014. The law (notably Article 9) also assigns a range of regulatory functions and responsibilities to other Georgian Ministries and organizations. However, there is a lack of explicit nuclear security provisions in the law. Regulations for the security of radioactive sources are under development.

According to the information in the INSSP, Georgia receives assistance from U.S., the United Kingdom and the IAEA for upgrading the security of radioactive sources.

2.9. Palliative Care

Considering that a significant number of patients have advanced cancer at the time of diagnosis and perish within a year, the delivery of quality palliative care is crucial. Palliative care (PC) is "an approach that improves the quality of life of patients and their families facing the problems associated with life-threatening illness, through the prevention and relief of suffering..." (WHO, 2002).

In oncology PC should be recognized as one of the four integral components of effective national cancer control programmes. PC is developed due to its humanitarian aspects, efficiency in controlling pathological symptoms and economic effectiveness.

Georgia has made good progress in the development of palliative care. The most important and fundamental step for the further development is to provide patients with oral forms of morphine for pain relief; educating health leaders, i.e. palliative care specialists; expanding education systems in palliative care among doctors and nurses; and creating palliative care centres.

The international classification evaluates the degree of development of palliative care into following groups:

1 – No known hospice or PC activity,
2 – Capacity building activity,
3 – Isolated (3a) or generalized (3b) palliative care provision,
4 – Preliminary (4a) or advanced (4b) integration PC into mainstream service

Georgia belongs to Group 3b: Generalized palliative care provision.

The aim is to achieve PC integration within the mainstream medical care in the country (Group 4a and 4b). Methods for achieving such a goal are considered by the national leaders of palliative care, in collaboration with international organizations and their experts. This is how the *Georgian National Programme for Palliative Care Action Plan for 2011 – 2015* (hereafter 'Programme') was created**.** The Programme was approved by the Healthcare and Social Affairs Committee of the Georgian Parliament.

The Programme justifies the desirability of developing palliative care, its most important aspects and methods of evaluation. The Programme evaluates the need for PC and pain relief treatment in the country, and finally highlights key areas of action, timelines and required resources.

In several visited hospitals palliative care units are not available. The availability of this important resource is increasing and should be further promoted considering the often late diagnosis of tumours and therefore the frequent need for symptomatic therapies.

Availability and accessibility of opioids

In Georgia, the pain medications for cancer pain treatment comply with WHO guidelines referred to as the *WHO Three Step Analgesic Ladder*. On July 10, 2008, the Minister of

Labour, Health and Social Affairs signed a normative decree to change opioid prescription forms and instituting more liberal prescription policy.

I step: Non-opioids: Paracetamol and numerous preparations from the NSAID group.
II step: Tramadol; WHO also recommends codeine, which, however, is not available in Georgia.
III step: Strong opioids.

Georgian patients have access to basic strong opioids, such as morphine injections, slow release and immediate release tablets and transdermal fentanyl. Transmucosal fentanyl preparations are not available. Immediate-release oral morphine preparations are used for the treatment of break-through pain. For cancer patients strong opioids are provided free of charge. In short, Georgia provides patients with oral morphine and transdermal fentanyl which is an important milestone for national palliative care.

Methadone is available only in substitution programmes for drug dependents. Opioids require special prescriptions by oncologists and by general practitioners. Doctors prescribing opioids must register such activities, and the procedure is simple and does not pose a significant barrier to accessibility of the analgesics. This is similar to the practice of pharmacies dispensing opioids. A general physician may prescribe the amount of opioid needed for one week (regardless of the daily dose) at a single visit. The prescription may be picked up at the pharmacy by a family member. In short, the most important opioids are available in the country, medications are free of charge for patients and the administrative provisions do not restrict access.

Georgia is still considered to be a country with very low consumption of opioid analgesics. In 2010, consumption of morphine (and equivalents) per capita was 2.2 mg, while the calculated requirement should be 164 mg. In addition, compared with 2006, in 2010, consumption has decreased by over 10% (Duthey *et al* 2014)**.** According to local PC staff the amount of morphine consumed in 2007 is about one-third to one-quarter of the estimated need.

According to physicians administrative restrictions do not present significant barriers to accessibility of opioids. A possible challenge is lack of knowledge about the use of opioids for pain management by primary care medical professionals who deliver medical home care to the terminally ill. In addition there is general opioid phobia and low awareness among patients and their family members which further compounds the challenge**.**

Immediate actions to improve pain management in Georgia should focus on educational activities for doctors and nurses; implementation of national analgesic recommendations for oncologists, family practitioners and palliative care specialists.

Education and training

Georgia has a group of palliative care specialists who are able to establish and implement PC training programmes. These specialists would be cooperating with partner organizations, such as the Institute of Palliative Medicine and Hospice in the USA and the Open Society Institute. These organizations have supported the postgraduate training programme. Two specialists (fellows) from Georgia have been trained at The Institute of Palliative Medicine and Hospice of San Diego (USA).

In 2008, palliative care was recognized as a subspecialty for the internist, oncologist, general surgeons and critical care physicians, and since 2014, for general practitioners (family physicians), neurologists, paediatricians and infectious diseases specialists. Currently, about 20 doctors have such a specialization and an additional 5 will complete specialization in the fall of 2014.

Since 2006 PC was incorporated in the educational curricula of three Medical Universities as a mandatory (Tbilisi State University) or voluntary (Tbilisi State Medical University and Batumi State University) courses.

There are Georgian PC Handbooks available for medical and nursing students.

Availability of palliative care services

The Georgian *National Programme for Palliative Care (Action Plan for 2011 – 2015)* estimates that, "with the current experience, we would recommend between 80 and 100 beds per million of inhabitants as the optimum level, if the non-cancer patients are also to be included. In relation to the preferred location, our experience indicates that the 20-30% of beds should be placed in acute hospitals, 50-60% in the social-health sector (also called medium-stay centres) and another 20-30% in the sector of nursing homes or homes of rest for the elderly".

Considering the above schemes, the Georgian model requires up to 30 hospital (in-patient) Palliative Care units and up to 35 mobile teams for home-based Palliative Care. This should include the Family Medicine Centres and rural out-patient clinics.

The current health care system would not be able to attain this goal. Currently in Tbilisi there is one in-patient palliative care centre with 18 beds plus 4 beds for HIV patients.

This Unit is located in the Universal Medical Centre in Tbilisi. It is run by a team of palliative care specialists and collaborates with the Oncology Centre; the latter has no beds. The Centre hosts palliative care training for the Tbilisi State Medical University.

In 2004 the Patriarchate of Georgia founded a 6-bed hospice in Tbilisi. The hospice also provides home care for 50-60 patients and has one doctor specialist in palliative care and 10 nurses. There are also volunteers recruited from the Medical University. The Hospice carries out a training programme for nursing assistants.

Palliative care is also available in a privately owned Medulla Centre. Palliative care is provided as part of cancer treatment. In addition to the residential care (30-35 patients over six month period), the centre organizes home care for 8-10 patients, if necessary. Palliative care is the responsibility of an oncologist who will finish a specialized training programme in palliative care in the fall of 2014. The team also consists of nurses and a psychologist. Medulla is a leading centre for conducting clinical research in oncology, including research of patient support and analgesic drugs.

The M. Iashvili Central Children's Hospital has 4 palliative beds at the onco-hematology ward and the Batumi Oncology Centre (Branch of the Tbilisi Oncology Centre) has 10-15 palliative care beds.

The Government supported home-based palliative care programme was instituted in 2004. During its peak period the programme consisted of 14 mobile teams active throughout Georgia. Each team consisted of 1 doctor and 3-4 nurses for every 25 patients. In 2012, significant reduction in funding resulted in the programme’s collapse. The programme currently operates in five regions covering not more than 5 patients per region.

3. TECHNICAL RECOMMENDATIONS

In the light of the discussions held, the following technical recommendations are put forth:

Cancer Control Planning

1. Create a national cancer control steering committee drawn from representatives in the Ministry of Labour, Health and Social Affairs, the National Centre for Disease Control and Public Health, relevant health centres / professionals and other relevant national stakeholders. Convene regular meetings to review, monitor and evaluate the progress of the *Cancer Control Action Plan 2015-2018*.
2. Review and revise *National Cancer Control Strategy 2013-2018* and *Cancer Control Action Plan 2015-2018* with appropriate phased targets and budget allocations.
3. Develop a human resource plan to support the *National Cancer Control Strategy 2013-2018* and *Cancer Control Action Plan 2015-2018*.

[WHO would take the lead in responding to requests for assistance in this area.]

Cancer Registration

4. Endorse all necessary documents for the establishment of the PBCR.
5. Amend Order #01-27/N "Production and Delivery Procedure of Medical Statistical Information" to ensure completion and submission of case notification form from all possible sources to the PBCR.
6. Establish detailed schemes and procedures of record linkages between PBCR database and potential sources of follow-up information, especially from mortality registry.
7. Explore collaboration opportunities between NCDC, IARC and IACR (International Association of Cancer Registries). Consider the translation and implementation of international guidelines on:
    - Incidence date, Multiple primaries, Basis of diagnosis
    - Confidentiality for Population-Based Cancer Registries
    - Data protection
    - Comparability and Quality Control

[For assistance required for recommendations within this area, please consult the International Agency for Research on Cancer – Regional Hub for Western Asia and Northern Africa, based at Izmir Cancer Registry (Turkey), which may be utilized for training and support for registry development.]

Prevention

8. Strengthen efforts to control overweight and obesity, to promote healthy diet and physical activity in daily routine activities through sustained health education among children and the general public.

Tobacco Control

9. The current tobacco control act should be implemented and enforced effectively to support comprehensive tobacco control measures aiming to curb all forms of tobacco use and to effectively implement all aspects of FCTC to which Georgia is a signatory.
10. Implement sustained health education on harmful effects of tobacco use in schools and among the general public.
11. Tobacco taxation should be substantially increased as stipulated in the FCTC, so that the excise taxation on finished tobacco products reaches 67-80% of the retail prices.
12. Allocate a proportion of the increased tobacco tax revenue to support cancer prevention, early detection and treatment services.
13. Effective measures should be taken to prevent smuggling of tobacco products from neighbouring countries; address cross-border issues in tobacco taxation through collaboration with neighbouring countries.

Alcohol Control

14. Implement sustained health education on harmful effects of all forms of alcohol consumption in schools and among the general public.
15. Develop a national strategic action plan to prevent and reduce alcohol consumption by focussing on increased taxation, ban on alcohol advertising and promotion, introducing minimum age for purchase, restrictions on alcohol selling outlets and times of sales.
16. Establish prevalence and patterns of alcohol consumption and conduct an economic analysis of the direct and indirect costs of alcohol consumption as a tool for advocacy towards policy makers.

Prevention and control of Hepatitis B virus (HBV) and Hepatitis C (HCV) infection

17. Reach the coverage of HepB3 dose above 95% by continuing to use the pentavalent vaccine and by adapting appropriate logistics.
18. A representative HBsAg serosurvey using rapid HBsAg tests may be conducted at regular intervals to evaluate the impact of the vaccination programme.

19. Introduce and follow strict guidelines of disinfection and sterilization procedures of medical instruments to improve the control of HCV infection.
20. The use of disposable needles for ear-nose-body piercing need to be promoted through public awareness programmes as a preventive strategy.

Prevention of HPV infection and cervical cancer by HPV vaccination

21. Since Georgia has limited data on HPV infection in the general population, a well-planned HPV prevalence survey should be conducted.
22. Include HPV vaccination in the future plans for the national immunization programme, utilizing the GAVI route, targeting 11 year-old girls through a school-based programme, which will result in a large cohort of women at low risk for cervical cancer in future.
23. After HPV vaccination is successfully implemented for 11 year-old girls, a catch up vaccination targeting girls up to 18 years may be considered
24. Plan and implement a HPV sentinel surveillance system to monitor coverage and assess impact of HPV vaccination before initiating HPV vaccination as part of the national immunization programme.

[WHO would take the lead in responding to requests for assistance in this area.]

Early Detection

25. To foster early diagnosis, efforts should be focused on improving population and professional awareness of the early symptoms and signs of common cancers such as breast, lung, colorectal and cervix. Empower primary care practitioners and nurses in the early recognition of people with suspected cancer symptoms and signs and strengthen the referral pathways to tertiary care institutions to ensure early clinical diagnosis and prompt and adequate treatment.
26. Strengthen the capacities of the existing personnel and health services such as central cytology laboratory and train screening staff such as radiographers, radiologists, ultrasonographists, colposcopists, endoscopists and colonoscopists.
27. A comprehensive information system should be developed and implemented to monitor and evaluate the impact of early detection programmes. Although computerised databases exist in some centres, currently the screening information in primary care is captured in hand written registers only and there is no plan for any coordinated information capture.
28. To ensure the sustainability of the early detection programme, the available resources should preferably be used for planning, prioritizing, feasibility testing and piloting since a full programme (breast, cervical and colorectal cancer screening) seems

difficult to achieve. Also, target ages and intervals for cancer screening should be reconsidered based on the available resources and sustainability.

29. Consider starting organised screening with a single screening programme and once this is operating effectively, the infrastructure and systems can be progressively expanded to include other cancers.
30. HPV vaccination at the national level is recommended.
31. Systematic PSA testing and other cancer markers testing are not recommended.

[WHO and IARC would take the lead in responding to requests for assistance in this area.]

Diagnosis and Treatment

32. Establish a Cancer Care Quality Board consisting of representatives of governmental institutions and cancer care stakeholders. Under the Cancer Care Quality Board a system of cancer care commissions per cancer localization should be established. Currently, there is no clear aim to assess current state of the Cancer Care System through Clinical Audits.
33. Elaborate and continuously review quality criteria for cancer care (by localizations as well as specialties, including accessibility requirements, performance and outcome criteria, time criteria, workload criteria, etc.). Additional considerations should be specialty (and subspecialty) education and training, health technology assessment, lifecycle of medical technologies, medicine policy, financing of health care services, as well as screening, prevention and palliative care.
34. The development of a national radiotherapy plan should be integrated in the NCCP. In the longer term (10 year timeframe) Georgia should consider to increase the radiotherapy capacity to approximately 11 units[35] (for distribution see Figure 2).
35. Consider developing private-public partnerships in order to make the radiotherapy accessible to the broader population (especially curative intent treatments).
36. Centralize paediatric radiation oncology service and train a team specialised in paediatric radiation oncology.
37. Raise awareness about modern radiotherapy among medical professionals in order to optimize referral patterns.
38. In regard to the new radiotherapy department at the Research Institute of Clinical Medicine (Todua Centre), in accordance with international standards patients should be treated on a new unit only after the unit has been commissioned and the commissioning results have been verified by an independent dosimetry audit or peer reviewed.

[35] This will depend on the actual demand for radiotherapy services in the next 10 years.

39. Implementation of technologies that might facilitate cancer care might be considered: Sentinel Lymph Node Detection Techniques, EPR and PACS.
40. Explore IAEA technical cooperation opportunities for human resources development (fellowships, scientific visits, expert missions, training courses, etc.) and the improvement of the quality of diagnostic and treatment modalities (comprehensive audits, such as QUANUM, QUATRO and QUADRIL).
41. Consider including specific nuclear medicine procedures in the state health insurance or other scheme. Currently, nuclear medicine procedures are not covered by state health insurance (excluding paediatric patients) and, neither by most of the private health insurers.
42. Consider revision, upgrade or development (if non-existent) of training programmes for radiotherapy and nuclear medicine professionals.

[WHO would take the lead in responding to requests for assistance in this area. Support for recommendations relating to radiation medicine may be provided by the IAEA and may be used as a basis for the formation of an IAEA Technical Cooperation project.]

Radiation Safety

43. The Government should consider the relative merits of revising the 2012 law and issuing two other laws on waste and transport, against the drafting and promulgation of a comprehensive law with a new body of regulations and thereafter, give clear direction to MENRP / DNRS.
44. MENRP / DNRS should urgently revise existing and/or issue new regulations to cover the spectrum of regulated activities in Georgia.
45. MENRP / DNRS should consider the development (with IAEA support as appropriate) of a structured national training programme and continuous professional development programmes for regulatory staff and others working in the field of radiation safety and security of radioactive sources.
46. MENRP / DNRS should consider a request for IAEA support with the development of a management system for the regulatory body, including formal procedures for the regulatory functions in accordance with best practice. An IAEA national workshop on the implementation of an integrated management system may be appropriate.

[The IAEA would take the lead in responding to requests for assistance in this area.]

Palliative Care

<u>Integrate palliative care in the existing structures of the national Health care System</u>

47. Taking into account the assessment contained in Georgian *National Programme for Palliative Care (Action Plan for 2011 – 2015)*, introduce the concept of palliative care in the *National Cancer Control Strategy 2013 – 2018*.
48. Gradually introduce palliative care services (including mobile support teams and pain clinic) and / or palliative care units in Regional Central Hospitals.
49. Expand the duties of general practitioners/family doctors with direct participation in home care and quality control.
50. Increase the range of competences and autonomy of district/home care nurses to administer palliative care.
51. Reassess financing of the home care programme, especially the involvement of nurses in the care and increasing their competence.

Improve the availability and consumption of opioid analgesics

52. Establish national guidelines, standards and protocols for pain therapy and palliative care.
53. Organize a system of postgraduate mandatory training in palliative care and pain management for oncologists, general practitioners/family doctors and district nurses.
54. Gradually limit remaining administrative barriers and reduce stigma associated with opioids (special form of prescriptions, weekly limit) and make available new relevant new drugs.

[WHO would take the lead in responding to requests for assistance in this area.]

References

[1] F. Bray, A. Znaor, P. Cueva, A. Korir, R. Swaminathan, A. Ullrich, S.A. Wang, and D.M. Parkin. Planning and Developing Population-Based Cancer Registration in Low- and Middle-Income Settings (IARC Technical Publication No. 43), Lyon: IARC 2014 Available from http://www.iarc.fr/en/publications/pdfs-online/treport-pub/treport-pub43/index.php

[2] F. Bray, D.M. Parkin. Evaluation of data quality in the cancer registry: principles and methods. Part I: comparability, validity and timeliness, Eur J Cancer, 2009, **45**(5), p. 747–755

[3] D.M. Parkin, F. Bray. Evaluation of data quality in the cancer registry: principles and methods. Eur J Cancer, 2009, **45**(5), p. 756–764

[4] J.E. Tyczynski, E. Démaret, D.M. Parkin Standards and Guidelines for Cancer Registration in Europe (IARC Technical Report, No 40), Lyon: IARC 2003

[5] Recommendations issued by ENCR. Available from http://encr.eu/index.php/activities/recommendations

[6] Lynch T, Clark D, Connor SR. Worldwide Palliative Care Alliance Mapping levels of palliative care development: a global update 2011. Worldwide Palliative Care Alliance 2011

[7] Kordzaia D, Dalakishvili S, Gvamichava R, Rukhadze T, Abesadze I, Dzotsenidze P, Gagua R, Tsertsvadze T, Javashvili G, Jincharadze M, Aladashvili T, Turkadze M. Georgian National Program For Palliative Care (Action Plan for 2011 – 2015)

[8] Duthey B, Scholten W. Adequacy of opioid analgesic consumption at country, global, and regional levels in 2010, its relationship with development level, and changes compared with 2006. Journal of Pain and Symptom management 2014, **47**: p.283 – 297

Cancer Control Resources

World Health Organization

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

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): http://www-dep.iarc.fr/
- Cancer Screening and Prevention: http://screening.iarc.fr/
- Global Initiative for Cancer Registry Development (GICR): http://gicr.iarc.fr/
- Regional Hub for Western Asia and Northern Africa, based at Izmir Cancer Registry (Turkey): Dr Sultan Eser (sultan.eser@gmail.com)
- Monographs on the Evaluation of Carcinogenic Risks to Humans: http://monographs.iarc.fr/

International Atomic Energy Agency

- Human Health Campus: Resources and Learning for Health Professionals: http://nucleus.iaea.org/HHW/Home/index.html
- *Planning National Radiotherapy Services: A Practical Tool*: http://www-pub.iaea.org/MTCD/publications/PDF/Pub1462_web.pdf
- *Setting Up a Radiotherapy Programme: Clinical, Medical Physics, Radiation Protection and Safety Aspects*: http://www-pub.iaea.org/MTCD/Publications/PDF/pub1296_web.pdf
- *Radiotherapy Facilities: Master Planning and Concept Design Considerations:* http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1645web-46536742.pdf
- Further publications related to nuclear medicine and diagnostic imaging: http://www-naweb.iaea.org/nahu/NM/publication.html
- Further publications related to applied radiation biology and radiotherapy: http://www-naweb.iaea.org/nahu/ARBR/publication.html
- Further publications related to dosimetry and medical radiation physics: http://www-naweb.iaea.org/nahu/DMRP/publication.html

Annex 1 – Mission Programme

Time	Activities	Remarks
Sunday 6 July		
	Team arrivals to Tbilisi on 6 and 7 July Counterpart pick up of experts and transfer to "Hotel Copala"	
Monday 7 July		
9:30 10:00 11:30 13:00 13:45 15:00 17:00 19:00	*Hotel departure* **National Liaison Office** Mr George Nabakhtiani (g.nabakhtiani@moe.gov.ge) Lunch **UNFPA** Breast and cervical cancer screening project, donor funding of NCDs/cancer Lela Bakradze, Assistant Representative of UNFPA Office in Georgia **WHO Country Office for Georgia** Dr Rusudan Klimiashvili WHO Representative for Georgia **Tobacco conference** Hotel "Holliday Inn" **USAID Project team** Nino Berdzuli, Head, JSI country office **Ministry of Health, Labour and Social Affairs of Georgia** Meeting with Heads responsible for Disease Control, Public Health System, Budgeting and Finance Dmitry Makhatadze, Deputy Minister	
Tuesday 8 July		
9:30 10:00	**Team Departs from Hotel** **National Centre for Disease Control and Public Health (NCDC)** (imPACT Mission Team meets with national counterparts / experts in each area of cancer control. During this session, the national counterparts / experts give a short, 15-minute presentation, in English language) on the national situation of activities, capacities and needs in each area of cancer control.) *Country Presentations on following topics:*	The objective of the presentations is to provide a broad overview of the national situation in the country. It is strongly recommended that presentations are given by professionals working in each specific area

	1. **Overview and Cancer Control Planning in Georgia** *(presented by member of National Cancer Control Coordinators / Committee) Dr Nana Mebonia* 2. **Cancer Information/Registration (cancer incidence and mortality data, hospital based registries)** *(presented by Dr Nana Mebonia, NCDC)* 3. **Cancer Prevention and Early Detection (early diagnosis & screening)** *(presented by Dr Rema Ghvamichava, National* Screening Centre) 4. **Diagnosis: clinical laboratory, pathology, radiology/nuclear medicine** **Path-anatomic research** *(presented by Dr Gia Burkadze)* **Radiology/nuclear medicine** *(presented by Shorena Esiashvili , Universal Medical Centre, Department of nuclear oncology, medical treatment and paediatric oncology)* 5. **Surgery** *(presented by Dr Baadur Mosidze, Centre of High Medical Technologies, University Clinic)* 6. **Medical oncology** *(presented by Dr Nia Sharikadze, Medical Clinic MediClubGeorgia)* 7. **Radiation oncology** *(presented by Dr Darejan Lomidze, Centre of High Medical Technologies, University Clinic)* **LUNCH** 8. **Palliative care** *(presented by Dr Soso Abesadze, Oncoprevention centre)* 9. **Radiation Safety** *(presented by Mr* George Nabakhtiani*)* **Question and Answer / Discussion**	describing 1) current situation (existing services and interventions), 2) achievements, 3) gaps/needs, 4) national priorities and 5) challenges and way forward.
14:00 17:00 17:00	**National Cancer Centre (NCC) / Universal Medical Centre – Dr Nato Shengelia (link)** *(short introduction to the centre provided by Director, followed by team members going to the following departments / sections of centre for discussions and assess capacity and needs)* • Cancer Registry • Prevention / Early Detection / Screening • Outpatient Clinic • Diagnosis (Pathology / Laboratory / Radiology) • Treatment (Radiotherapy / Chemotherapy / Surgery) • Palliative Care / Supportive Care **Ministry of Environment** Shalva Amirejibi, Deputy Minister	

	Catherine, Arsen **National Centre for Disease Control and Public Health** Department of Statistics, Department of State Programs, NCD Department Discuss national cancer registry system *Anton* **Teams Return to Hotel for Daily Debrief Meeting**	
Wednesday 9 July		
Depart Hotel for Kutaisi at 6:30 a.m. 9:00-9:30 11:00 12:30 14:00 10:00 12:00 13:00 16:30	***All day visit to Kutaisi sites*** *Arsen, Sergei, Alessio* **Saint Nicolas Centre of Oncology and Surgery** Chemotherapy, surgery *Arsen, Sergei, Alessio* **Academic Tskhakaia National intervention Centre of medicine of west Georgia** Screening, chemotherapy, surgery *Arsen, Sergei, Alessio* Lunch **Women's Health Clinic / NGO "Hera "** Screening *Arsen, Sergei, Alessio* ***Return to Tbilisi by 7 p.m.*** ***Tbilisi sites*** *Anton, Catherine* **Private Insurance Company "Aldagi"** Ivane Bokeria **State Insurance Company** MoH; Rusudan Gogolashvili **National Screening Centre**	

	Tbilisi Onco-dispensery Screening, surgery, chemotherapy Gitsa Gabunia, tel 577 463766	
Thursday 10 July		
9:00 12:00 13:00-14:00 14:30 16:00	**Tbilisi First Hospital / High Technology Medical Centre, University Clinic** *All* *(short introduction to the centre provided by Director, followed by team members going to the following departments / sections of centre for discussions and review of capacity and needs)* • Cancer registry / Medical Records • Prevention / Early Detection / Screening • Diagnosis (Pathology / Laboratory / Radiology) • Treatment (Radiotherapy / Chemotherapy / Surgery) • Outpatient services **Tbilisi State Medical University** *All* *Rima Beriashvili MD PhD; Vice-rector* **Lunch** **Iashvili Children's Central Hospital (link)** *Anton, Sergei and Alessio* • Cancer registry / Medical Records • Diagnosis (Pathology / Laboratory / Radiology) • Treatment • Referrals **Research Institute of Clinical Medicine (Todua centre) (link)** *All* • Cancer registry / Medical Records • Diagnosis (Pathology / Laboratory / Radiology) • Treatment • Referrals **Full Mission Team Meets for Debrief Meeting with WHO Country Office, NLO and imPACT mission focal points**	
Friday 11 July		

10:00	**NCDC Prevention/Registry**	
11:30	**Clinic "Medula"**	
13:00-14:30	**Lunch**	
15:00	**Closing Meeting with Deputy Ministers of Health** Mission Team to Provide Preliminary Findings and Recommendations	

Annex 2 – List of Persons Met

Ministry of Labour, Health and Social Affairs
Dimitri Makhatadze, First Deputy Minister
Mariam Jashi, Deputy Minister

National Centre for Disease Control and Public Health
Amiran Gamkrelidze, Director General
Lela Sturua, Head, Non-communicable Diseases Department
Nana Mebonia, Head, Chronic Diseases Unit
Nino Maglakelidze, Chief Specialist, Non-communicable Disease Department

World Health Organization
Rusudan Klimiashvili, WHO Head of Office, Georgia
Nino Mamulashvili, Programme Coordinator

United Nations Population Fund (UNFPA)
Lela Bakradze, Assistant Representative
Levan Jugeli, National Consultant, National Screening Centre

United States Agency for International Development, John Snow Inc. (USAID JSI Sustain Project)
Nino Berdzuli, Chief of Party

Ministry of Environment and Natural Resources Protection
Mariam Giorgobani, Main Specialist, Department of Nuclear and Radiation Safety

National Cancer Centre
Natalia Shengelia de Lange, Nuclear Medicine Physician
Research Institute of Clinical Medicine
Fridon Todua, Director

Universal Medical Centre
Gela Gogishvili, CEO
Liana Chumburidze, Head, Business Development

Tbilisi State Medical University
Rima Beriashvili, Deputy Rector

High Technology Medical Centre, University Clinic
George Ingorokva, Genberal Director

Hera Health Centre
Marine Davituliani, Director

West Georgian National Centre of Interventional Medicine

Koba Kiknavelidze, Medical Director

Annex 3 – Profiles of Georgian Cancer Centres and Hospitals

Profile Information	**National Cancer Centre Tbilisi**	**Saint Nicolas Centre Kutaisi**	**Tskhakaia National Centre, Kutaisi**	**High Technology Centre, Tbilisi**	**Iashwili Children's Centre, Tbilisi**	**Todua Centre Tbilisi**	**Oncology Centre Adjara, Batumi***
Number of cancer patients	> 2000	N/A	800	890	34	1000/year (TBC)	NA
Guidelines	Local	No	No	Work in progress	German	European	NA
Tumour boards	No	No	No	Yes	No	Yes (TBC)	NA
Quality Assurance audit	in preparation (TBC)	No	No	follow-up protocol	internal protocol	No	NA
Support services (psycho, rehabilitation)	Psychology for paediatric patients	No	No	Yes	Psychology, but no rehabilitation	No	NA
Surgical oncologists	Yes / 18	Yes / 5	Yes / 23	4	15	Yes / 20	NA
Operations/year	600	N/A	800	890	100	1600	NA
Video-laparoscopy / robotic	No	Yes / No	Yes / No	Yes / No	Yes	Yes	NA
Operation theatres	4	3	4	4	Yes	4	NA
Gastrointestinal	Yes	Yes	Yes	Yes	Yes	Yes	NA
Gynaecologic	Yes	Yes	Yes	Yes	Yes	Yes	NA
Urologic	Yes	Yes	Yes	Yes	Yes	Yes	NA
Neurosurgery	No	No	N/A	Yes	Yes	No	NA
Paediatric	Yes	No	No	Yes	Yes	No	NA
Other	Breast	Breast	Breast	Thoracic	Yes	Breast	NA
% curative	N/A	100 (TBC)	65%	65 %	NA	NA	NA
% palliative	N/A	0 (TBC)	35%	35 %	NA	NA	NA
CHEMOTHERAPY/medical oncologists	Yes / 6	Yes / 1	Yes / 3	3	5	2	NA
Oncology nurses	6	1	3	2	10 trained	2	NA
Oncopharmacists	No	No	No	0	No	No	NA
Safety measures	No	No	No	Yes	Yes (TBC)	Yes	NA
RADIOTHERAPY	Yes	No	No	Yes	Referred to High	No	NA

					Technology Centre		
Waiting time (days)	0			15		#	NA
Patients/year	1500			1044		#	NA
% palliative/curative	40 / 60			50 / 50		#	NA
Techniques : 2D, 3D, IMRT, IGRT, TBI, HBI, SRS)	2D			3D, IMRT (H&N prostate) §		Equipped x 3D, IMRT, IGRT, SRT §	NA
Cobalt-60 units	1			No		No	0
Linac	0			2		2	1
Brachytherapy (HDR, LDR, isotope)	HDR, 192-Ir (400 pts/year)			HDR (192-Ir, Gyn) LDR (125-I, prostate.)		No	Yes (TBC)
Simulator	1			No		0	NA
CT-simulator	0			1		1	NA
MLC	0			1		Yes	NA
EPID	0			Yes		Yes	NA
R&V	0			Yes		Yes	NA
Mould room	1			Yes		No	NA
Immobilization devices	1			Yes		Yes	NA
TPS (2D, 3D)	2D			3D		3D	NA
Radiation oncologists	10			5		3	2
Medical physicists	3			5		5	0
RTTs	9			11		4	1
Radiation oncology nurses	9			4		0	NA
Repair/maintenance (engineers/contract)	Local staff			Contract + local staff		Contract	NA
Palliative care	Yes	No	No	No	Yes [@]	Yes	NA

Abbreviations: § Stereotactic radiotherapy should be implemented in the next few months; # Regular clinical activity (radiotherapy treatments) should start in the next few months; @ Connected to a palliative care unit; * Centre not visited, data collected through the NCDC using the IAEA questionnaire; N/A: Not assessed or Not available; TBC: To be confirmed.

Annex 4 – Background Information

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 100 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 experiences 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

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 evidence base for international action on prevention and control of non-communicable diseases (NCDs), including cancer.

Given cancer's human and economic cost, 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, the *Cancer Prevention and Control Strategy Resolution*, was adopted by the World Health Assembly in 2005. The 2005 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, 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 in the WHO's web page[36].

In September 2011, the UN General Assembly convened for the *High-Level Meeting of the General Assembly on the Prevention and Control and Non-communicable Diseases*, a significant milestone in efforts to make international commitments that put NCDs high on the development agenda. In May 2013, the World Health Assembly endorsed the *WHO Global Action Plan for the Prevention and Control of Non-communicable Diseases 2013–2020*, and adopted the Global Monitoring Framework, including nine voluntary targets and 25 indicators.

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

IARC was established in 1965 as an autonomous agency of 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 support for the implementation

[36]http://www.who.int/cancer/nccp/planning/en/

of cancer prevention and early detection activities. The *Cancer Incidence in Five Continents* series[37], *GLOBOCAN*[38], *SURVCAN*[39], and the *International Incidence of Childhood Cancer*[40], produced by IARC's Cancer Information Section, are international reference sources of incidence, prevalence, mortality and survival. Through the *Global Initiative for Cancer Registries (GICR)*[41], 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[42]. 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.

Cancer Control Assessment Missions

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 the health system challenges and to effectively respond to the cancer pandemic, WHO has recommended the development of National Cancer Control Programmes (NCCPs), which are defined as "*a public health*

[37]http://ci5.iarc.fr/
[38]http://globocan.iarc.fr/
[39]http://survcan.iarc.fr/
[40]http://www-dep.iarc.fr/
[41]http://gicr.iarc.fr
[42]http://monographs.iarc.fr/

programme 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 the prevention, early detection, diagnosis, treatment and palliation, making the best use of available resources" [43].

To develop and strengthen NCCPs, 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 health care 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 – and integrated with – other critical elements of cancer control.

In view of the above, the IAEA offers, through its Division of Programme of Action for Cancer Therapy, a service to its Member States called the **imPACT** (integrated mission of PACT) **Review**. 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[44], within the framework of an NCCP. The **imPACT Review** is carried out, upon request from the Ministry of Health of a Member State, in consultation and close collaboration with WHO, IARC and other partners. Following an intensive data collection and research process, identification and nomination of experts for each cancer control area by the relevant partner, communication with the national counterpart and partners, the **imPACT Review** 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 Mission Report" submitted to the Minister of Health of the requesting Member State. The report is endorsed by participant organizations and contains detailed findings and expert recommendations. Based on the report, the Ministry of Health is expected to develop a "Short to Medium

[43] *National Cancer Control Programmes — Policies and Managerial Guidelines: Second Edition* (WHO, Geneva, 2002): http://www.who.int/reproductivehealth/publications/cancers/9241545577/en/index.html.

[44] *Radiation medicine infrastructure assessment*: This involves an assessment of a country's radiation therapy and nuclear medicine capacity, practices and needs. This area is reviewed on the basis of relevant IAEA guidelines, with the technical backstopping of the IAEA Division of Human Health.
Additional references are: *"Setting Up a Radiotherapy Programme: Clinical, Medical Physics, Radiation Protection and Safety Aspects"* (http://cancer.iaea.org/documents/Ref5-TecDoc_1040_Design_RT_proj.pdf), and *"Planning National Radiotherapy Services: A Practical Tool"* http://www-pub.iaea.org/MTCD/publications/PDF/Pub1462_web.pdf).
Regulatory requirements refer to an assessment of radiation protection and regulatory services to ensure the safe and secure use of radiation and radioactive material when and where required on the basis of the IAEA safety and security standards, guidelines or codes of practice and the status of the Member State visited.

Term Action Plan" that may endeavour 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 WHO.