



MINISTRY FOR HEALTH

THE NATIONAL CANCER PLAN FOR THE MALTESE ISLANDS

2017 - 2021

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MINISTRY FOR HEALTH
MALTA

FOREWORD

Cancer remains a major cause of morbidity and mortality within our society. The annual mortality rate attributable to cancer in the Maltese Islands is reaching 29% of all deaths. Much has been achieved in the last few years in the management and care of cancer patients. The new specialized Oncology Hospital with cutting edge linear accelerators, together with a strong investment in human resources and the introduction of seamless cancer care pathways, have been game changers in the way we treat cancer. We now need to build on this success. This cancer plan details how we will be doing just this.

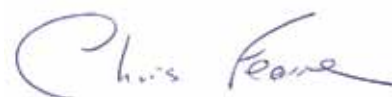


The addition of new cancer medicines to the Government Formulary in a planned and sustainable manner over the early years of this Plan will strengthen treatment options. Consolidation of the multidisciplinary approach to cancer care and the positioning of the patient in the centre of the care plan will allow our patients to receive the best care in all of its aspects.

The advent of precision medicine is making cancer care a more and more personalized affair, with targeted, tailor-made treatments. This calls for increased research efforts. The National Cancer Plan proposes a Cancer Research Foundation to coordinate and lead cancer research in the Maltese Islands.

As the Maltese population grows demographically older and the incidence and prevalence of cancers increases, prevention becomes even more important. This Plan outlines the efforts we, as a national health system, need to dedicate to prevention. Indeed, resources and financing channelled directly towards prevention will be significantly increased during the term of this plan.

The targets set out by this National Cancer Plan are ambitious. However, I am confident that given the dedication, competence and clinical skills of our professionals these targets will be met to the benefit of our patients and society.



Chris Fearne
Minister for Health

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EXECUTIVE SUMMARY

A total of 1800 individuals are now diagnosed with cancer every year in Malta and this is expected to continue rising and surpass 2100 new diagnoses per year by 2020. This incessant rise in cancer incidence is the result of a combination of factors including people's lifestyle choices that put them at risk of cancer such as smoking and environmental exposure to carcinogens. Furthermore, due to the successes of the health care and social care systems, people are living longer and as a result, the lifetime risk of developing and being diagnosed with cancer is continuously expanding. Increased longevity coupled with improved survival rates for certain types of cancers is also leading to a growing population of persons living with or beyond a cancer diagnosis.

This National Cancer Plan sets out an integrated and comprehensive plan of action for the next five years (2017 to 2021). It will continue to build on the successes of the first National Cancer Plan and address pending and emerging new challenges in cancer control. Among the challenges are the inevitable increase in demand for cancer care services generated by the rise in incidence and prevalence of cancer cases in Malta, and the consequent rise in cancer care costs which is further compounded by the rapidly evolving and increase in the sophistication of cancer treatments available and relentless emergence of expensive innovative medicines.

The ultimate aim of the National Cancer Plan is to improve a number of identified outcomes that are important for both the patients and society. These include the:

- A. Reduction of cancer incidence**
- B. Improvement of cancer survival**
- C. Improvement of patients' experience and quality of life.**

Cancer prevention, especially when integrated with prevention of chronic diseases offers the most cost-effective long-term strategy for the control of cancer. A considerable number of cancer cases can be prevented if people adopt healthier lifestyles. To this end, a number of preventive strategies are aimed at continuing the fight to reduce tobacco consumption and passive exposure to tobacco smoke, control alcohol consumption, decrease sedentary lifestyles and further promote the adoption of healthy eating and body weights. Cancer risks posed by infectious agents and exposures to carcinogens in the environment and at work are also being addressed. Furthermore, in order to also address health inequalities in our society, preventive measures will seek to target selected vulnerable groups e.g. children and young people and people working in high risk occupational settings.

Early detection of cancer greatly increases the chances for successful treatment outcomes and improved survival. There are two major components for early detection in cancer: education to promote early diagnosis and screening. There are three organised and population-based national cancer screening programmes operating in Malta; for cancers of the female breast, large bowel and cervix of the uterus. Support for these programmes will continue to be strengthened with the aim of continually increasing the attendance rates for these screening programmes and

the number of invited persons. This cancer plan will also seek to provide more support and training opportunities to family practitioners and other health care professionals (HCPs) so that they become better able to recognise 'red flags' and to take the necessary actions including referral to specialist care when indicated. This will be complemented by increasing activity to improve the timeliness of the initiation of the diagnostic processes through measures such as the implementation of fast-track referral tools and systems.

Once cancer is detected, a substantial proportion of patients will require access to a combination of diagnostic services including pathology and imaging interventions for diagnosis and staging, followed by combinations of surgery, radiotherapy and chemotherapy as primary treatment. A number of patients will also require the management of progressive or recurrent disease and end-of-life care. This cancer plan adopts an integrated care approach to improving the provision of each of these diagnostic and treatment modalities and also reduce discontinuity and lack of co-ordination of care by strengthening coordination between and within specialised/secondary and primary health care. This will ultimately enhance not only survival but also the quality of life of cancer patients during and after the completion of acute cancer care. Care plans for rehabilitation, psycho-social and palliative care needs and the special needs of cancer survivors need to be an integral part of the continuum of care, from the onset of the disease. Furthermore, the Plan is backing the further development of multi-disciplinary care, and systems that can facilitate the transfer of specialised knowledge and expertise both within the local healthcare community as well as with cross-border expertise when required. The latter can be of particular importance for the improved management of people with a rare cancer diagnosis.

Research is another priority area of this National Cancer Plan. A number of initiatives are envisaged with the aim of increasing opportunities and boosting the infrastructure for research concerning various aspects of the cancer care pathway including; ongoing cancer surveillance, research in molecular science and genetics, evaluation of patient outcomes and of cancer services including cost-effectiveness studies. Monitoring of progress in the cancer care services in Malta over the next five years and the implementation of this National Cancer Plan in particular will be done using a set of pre-identified indicators.

The implementation of this Plan will necessitate intense collaboration and joint working with all stakeholders whose efforts have the potential to directly or indirectly contribute towards the achievement of its overarching aims. The National Cancer Plan cannot be developed, implemented and monitored in isolation but needs to be taken forward in tandem with other strategies and developments in the health sector.

This integrated plan for action is a challenging and ambitious strategy. It will necessitate considerable and augmented investment in both physical and human resources. Despite this, Government is committed to proceed with the launch and implementation of this Plan as it acknowledges the need to constantly upgrade and update the national cancer control services so that improvements in the national cancer control outcomes continue to be registered.

CHAPTER 1

THE CURRENT LANDSCAPE OF CANCER IN MALTA

This chapter is divided into three major sub-sections:

- A. Epidemiological landscape
- B. Social and individual patient perspectives
- C. Economic perspectives: the economic case for cancer control services

A. EPIDEMIOLOGICAL LANDSCAPE

Every 5 hours someone in Malta will be told they have been diagnosed with a cancer. A total of 1800 individuals are now diagnosed with cancer every year. This number is expected to continue rising by around 1.5-2.0% per annum (Coleman et al., 2008). Around half of these diagnoses will be of the most common cancers – breast, lung, prostate, and colorectal – and the other half will be of less common or rare types. Figure 1 shows that projecting onto the current growth trends, **cancer incidence** is expected to surpass 2100 new diagnoses per year by 2020, and approach 2500 annually by 2030.

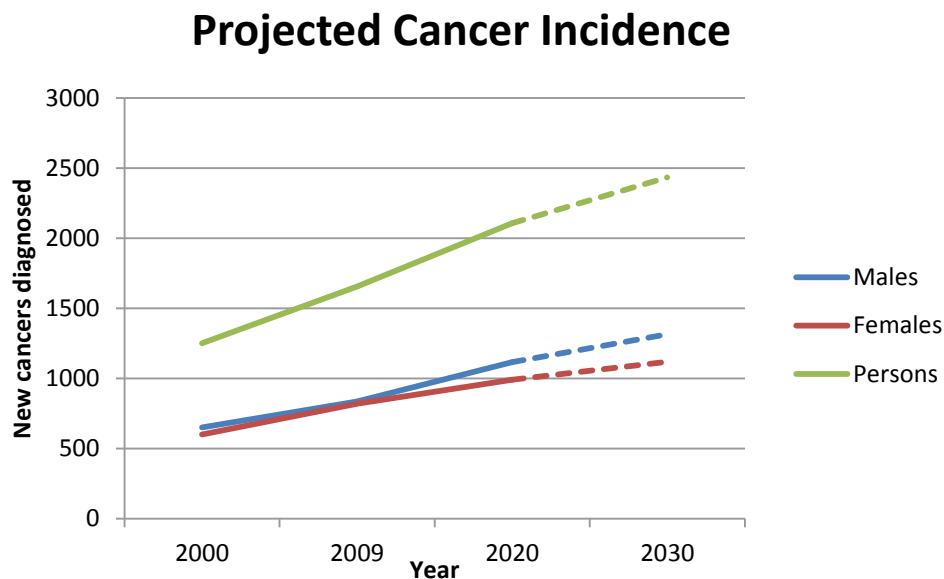


Figure 1: Projected increases in the number of new cancer diagnosis per year up to 2030
(Source: Malta National Cancer Registry, Directorate for Health Information and Research, 2016)

Generally, the overall achievements of the healthcare and social care systems are to a notable extent leading to this evident incessant rise in incidence. These successes are leading to the demonstrable and continuous ageing and growth of the population as people are less likely to die early from other conditions, such as infections and cardiovascular disease.

However, the rise in cancer diagnoses is also in part being driven by changes in people's lifestyle choices. Some of these choices (such as smoking) are known to increase the age-standardised risk for cancers. These shifts often lead to rising demands on the health system, alongside demands resulting from the changing nature of other conditions. Long-term or chronic health conditions – rather than illnesses susceptible to a one-off cure – now can consume up to 70% of the health service budget (Timmins and NHS, 2014).

The **lifetime risk of developing and being diagnosed with cancer** is continuously expanding. Lifetime risk is a measure of how widespread cancer is expected to be in a particular population. Much of this increased risk can be attributed to increasing longevity.

A recent study published in the British Journal of Cancer (Ahmad, Ormiston-Smith and Sasieni, 2015) demonstrated that pending substantial changes in the current trends for cancer incidence, the lifetime risk of cancer for people in Great Britain born since 1960 is expected to exceed 50%. It can be assumed that the forecasted increasing trend will follow a similar pattern for populations living in other developed countries. Figure 2 replicates the same method (Sasieni cohort approach) to data available for the population in Malta (1995 onwards) on the cohort of people born in 1960. It is showing that at the age of 60 years (in 2020) their risk of being diagnosed with cancer will approach 35% for females and 40% for males.

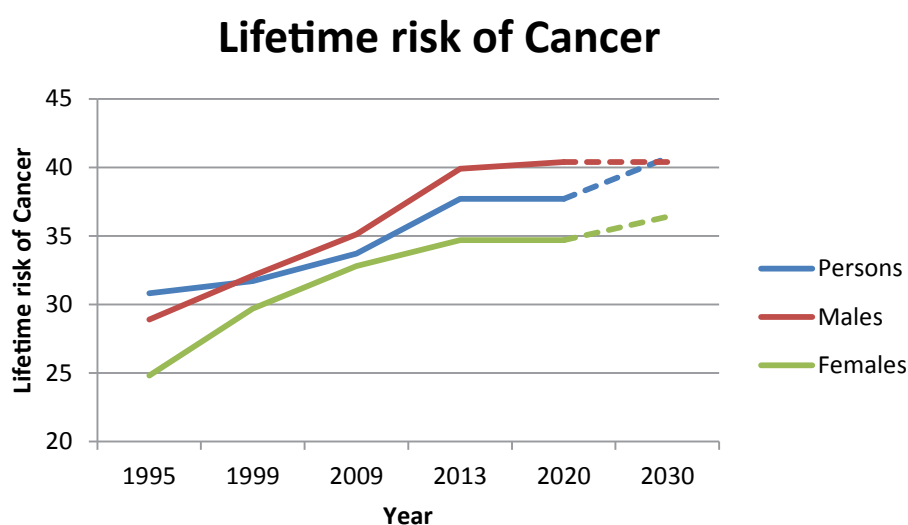


Figure 2: Lifetime risk for people born in 1960 for all cancers (excluding non-melanoma skin cancers) based on data from 1995 to 2013 and projected to 2030
(Source: Malta National Cancer Registry, Directorate for Health Information and Research, 2016)

On the other hand, **cancer survival** is continuously improving, with demonstrable and notable improvements made over the last two decades. The age-standardised ten-year survival from all cancers for patients diagnosed and managed in Malta is now approaching 50%. Figure 3 shows age-adjusted ten-year relative survival for all cancers combined and for a small number of major cancer sites. These rates were computed using the Ederer II method (Hakulinen, Seppä, and Lambert, 2011) and covers the population of cancer patients diagnosed between 2008 and 2012 and followed until end 2014.

Survival Trends

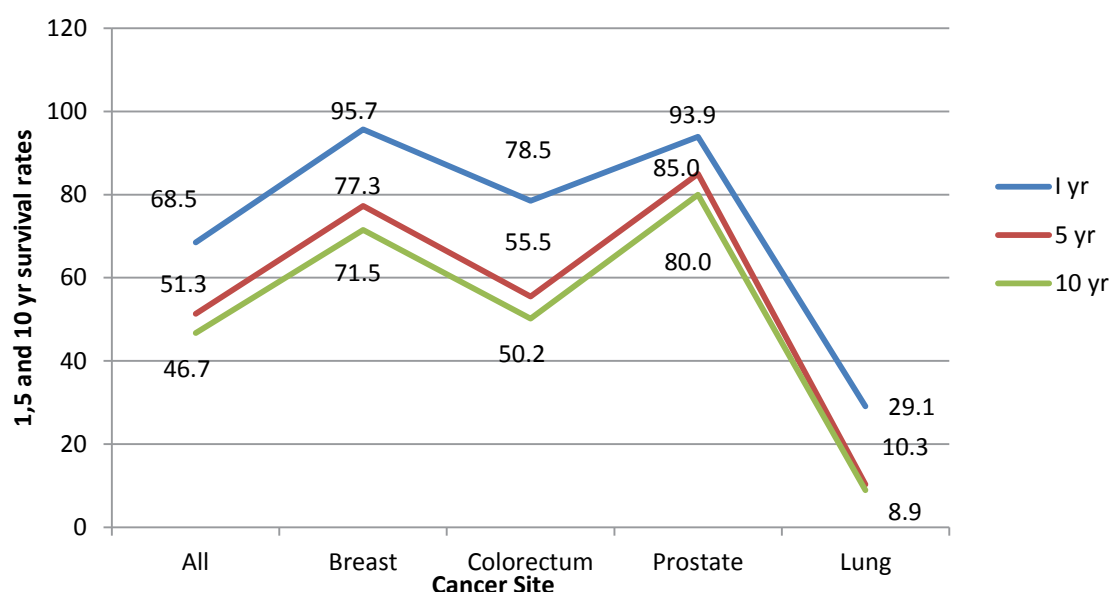


Figure 3: Age-adjusted ten-year relative survival for all cancers combined and for a small number of major cancer sites. Covers the population of cancer patients diagnosed between 2008 and 2012 and followed until end 2014 (Source: Malta National Cancer Registry, Directorate for Health Information and Research, 2016)

This means that around half of the group of people receiving a cancer diagnosis can now expect to live ten years or more after their diagnosis. This progress has been driven by improvements in the overall knowledge of how to control and treat cancer, combined with the commitment of the national health systems to deliver cancer control and care services that are persistently being expanded and upgraded.

Remarkable improvements in survival have been demonstrated for some types of cancer, notably malignant melanoma, breast, testicular, thyroid and prostate cancers. However, there are also clusters of cancer patients for whom outcomes in terms of survival, morbidity and quality of life have remained unchanged and are particularly poor. For example, to date survival has remained intractably low for patients diagnosed with cancers such as those of the lung, pancreas, stomach and specific types of acute leukaemias in adults as well as for most brain tumours.

Site	EUROCARE-4 [1995-1999]		EUROCARE-5 [2000-2007]		
	European Mean	Malta	European Mean (CI)	Malta (CI)	Best performer (CI)
Stomach	24.1	17.2	25.1 (24.8 – 25.4)	18.7* (14.2 – 23.6)	Iceland – 34.5 (27.8 – 41.3)
Colon	54.3	50.9	57.0 (56.8 – 57.3)	58.1 (53.4 – 62.4)	Germany – 62.2 (61.7 – 62.8)
Rectum	53.6	53.6	55.8 (55.5 – 56.1)	52.8* (46.5 – 58.7)	Iceland – 73.2 (65.2 – 79.6)
Lung	12.2	8.5	13 (12.9 – 13.1)	10.3* (7.9 – 13.0)	Austria – 16.7 (16.1 – 17.2)
Skin Melanoma	83.1	84.5	83.2 (82.9 – 83.6)	87.7 (78.7 – 93.1)	UK (N. Ireland) – 90.7 (88.1 – 92.8)
Breast (women only)	81.6	78.1	81.8 (81.6 – 82.0)	80.8* (77.0 – 84.0)	Iceland – 87.2 (83.1 – 90.4)
Ovary	41.9	38.4	37.6 (37.1 – 38.0)	39.3 (32.2 – 46.2)	Sweden – 44.1 (42.5 – 45.6)
Prostate	77.7	69.9	83.4 (83.1 – 83.6)	84.9 (79.0 – 89.2)	Austria – 90.4 (89.7 – 91.0)
Kidney	59.9	61.6	60.6 (60.2 – 61.0)	48.4* (39.3 – 56.9)	Austria – 71.4 (70.1 – 72.6)
NHL	55.0	62.7	59.4 (59.0 – 59.7)	47.8* (41.8 – 53.6)	Iceland – 74.1 (67.2 – 79.8)

Table 1: 5-year standardised relative survival for adult patients for a number of main cancer sites for Malta with comparable rates taken from the EUROCARE-4 (European average) and EUROCARE-5 (European average and best performer) studies

Notes:

- Data are % relative survival for adult patients with cancer (95% Confidence Intervals)
- European mean data are population-weighted means of the country specific relative survival estimates
- CI = 95% confidence intervals
- (*) and bold - survival rates for Maltese patients that are lower than the European average
- NHL = Non-Hodgkin's lymphoma

Table 1 compares cancer survival rates for a number of main cancer sites taken from the results of EUROCARE-4 (European average) (Sant et al., 2009) and EUROCARE-5 (European average and best performer) (De Angelis et al., 2014) studies and Malta. This table demonstrates that for the selected sites portrayed the survival rates for Malta are either below or near to the European mean (except for skin melanoma). Additionally, there is evident temporal improvement in the survival rates from the EUROCARE-4 to EUROCARE-5 studies for most of the sites, but a downward trend is manifested for the 5-year survival for cancers of the rectum, kidney and non-Hodgkin's lymphoma.

The findings of the two most recent European cancer survival studies (EUROCARE-4 and EUROCARE-5) and the CONCORD-2 (Allemani et al., 2015) study (worldwide surveillance of cancer survival), have thrown light on the European and global trends in cancer survival throughout the last two decades. In general survival increased steadily over time in most European and other developed countries, including Malta. In particular, the 5-year survival from colon, rectal, and breast cancers has increased steadily in most of these countries. The CONCORD-2 study shows that for patients diagnosed during 2005–2009, survival for colon and rectal cancer reached 60% or more in 22 countries around the world; and for breast cancer, 5-year survival rose to 85% or higher in 17 countries worldwide. On the other side of the spectrum, lung cancer remains lethal in all nations with 5-year survival persisting below 20% everywhere in Europe and in North America.

On average, between 2010 and 2014, cancer was the cause of 29.5% of deaths from illness or disease (excluding violent or accidental deaths). **Mortality from cancers** is constantly higher in men than in women. The highest proportion of deaths attributed to cancer over all deaths occurs in the 45 to 64 years age groups (on average amounting to 52% of all deaths in this age group between 2010 and 2014). Cancers diagnosed in this age cohort that comprises a very high proportion of economically and socially active persons have a high tendency of being highly malignant with resultant high morbidity and mortality leading to an exceedingly serious personal and societal socio-economic burden.

The number of people dying from cancer in Malta has increased slowly over the past 30 years. However, this rise is age specific and highly skewed towards increases in cancer deaths registered in the most elderly sectors of the population. Variations in cancer mortality also differ with different types of cancer in line with changes in the incidence of specific cancer sites and types. Around 900 to 1000 people in Malta still die from cancer each year. However, due to decreasing trends in the mortality rates for other causes, we can expect a projected increase in the proportion of deaths attributable to cancer over the next 20 to 30 years. Figure 4 shows that by 2040, cancer mortality is forecasted to reach approximately 35% of all deaths in females and 40% of all deaths in males.

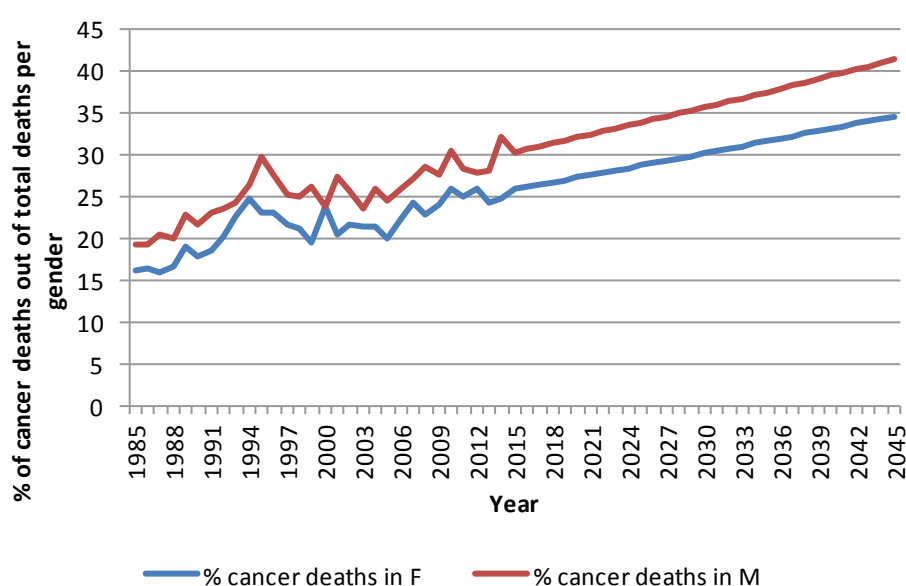


Figure 4: Projections of the percentage of cancer deaths over all-cause mortality by gender
(Source: National Mortality Registry, Directorate for Health Information and Research, 2016)

Figures 5a and 5b are statistical projections that show the major upward shift in cancer mortality expected in the older age groups (85+). On the other hand, there is an anticipated decrease in cancer mortality in the younger age groups. These forecasted trends will have important implications for the planning of healthcare for the most elderly segments of the population.

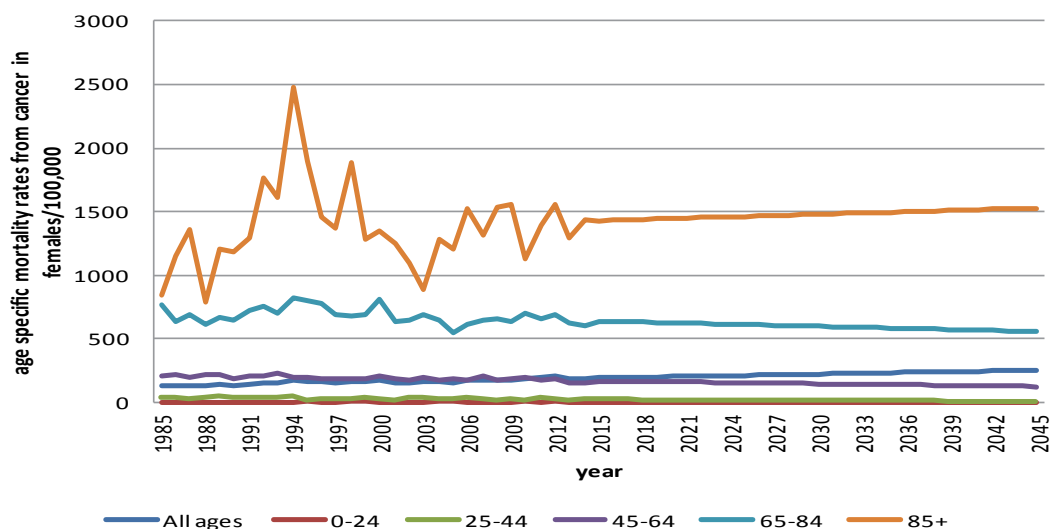


Figure 5a: Projections of age-specific mortality rates from cancer in females per 100,000 population
(Source: National Mortality Registry, Directorate for Health Information and Research, 2016)

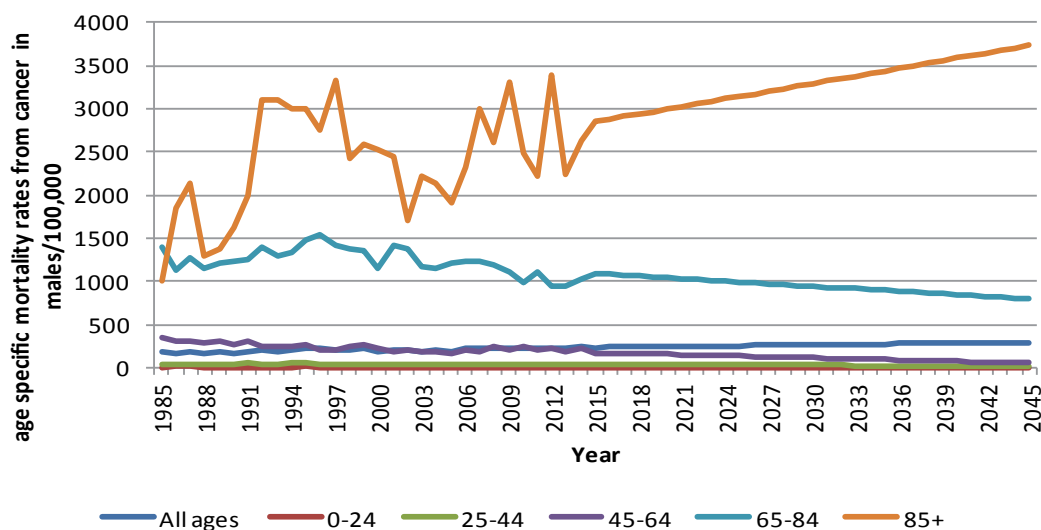


Figure 5b: Projections of age-specific mortality rates from cancer in males per 100,000 population
(Source: National Mortality Registry, Directorate for Health Information and Research, 2016)

As a consequence of the combination of the progress in survival and earlier detection, and an increasing and ageing population there is an increasing population of **persons living with or beyond a cancer diagnosis**. In 2012, there was an estimated 1451.2 persons per 100,000 population (or around a total of 6000 persons) who were diagnosed with cancer from 2008-2012 living in Malta (GLOBOCAN 2012). This represents an increase in cancer prevalence of about 2000 persons over the previous five years (2004-2008) and the number is projected to at least double by 2030 (Bray et al., 2012). Of all people living with cancer, prevalence is highest for patients that were diagnosed with cancer of the prostate in men and cancer of the breast in women.

B. SOCIAL AND INDIVIDUAL PATIENT PERSPECTIVES

Experiences recounted in the literature and from other countries have shown that there are **significant variations in the survival outcomes of patients in different socio-economic strata** and residing in different geographical areas. Several factors have been posited for these differences and include for example, differences demonstrated in the proportion of cancers diagnosed at an early stage through both screening or better awareness and the higher smoking rates among the more deprived sectors of the population. These health inequalities can be translated into the inference that there is substantial scope to persist in addressing potentially avoidable variations in survival outcomes.

The **experience and quality of life** that patients have throughout and beyond diagnosis and treatment is equally as important as the aspects of clinical effectiveness and safety. Patients' experience of and satisfaction levels with hospital treatment is another important aspect of cancer care that merits development and deeper deliberation. Considerable variability has been reported in the literature with generally poorer findings for the older and younger patients and patients with less common cancers (NHS England and Quality Health, 2015). Poor communication both in terms of the information given about their diagnosis and treatment options, and in the level of compassion and empathy that patients receive was reported as being the area requiring the greatest effort for improvement.

Traditionally, attention on the care received by patients after their initial treatment has been less forthcoming. For example, it is well known that patients who have been diagnosed with cancer have an increased risk of being diagnosed with another cancer in the future. **Many of the treatments contemporarily being used in cancer care have recognized potential for long-term physical and mental health consequences.** This results in a high proportion of individuals requiring successive and recurring health and social care support. There are also a number of recognized considerable and practical impacts for patients such as loss of employment and income and persistent dependency on other persons in their family and community. The lack of attention to these issues often leads to poorer quality of life for patients and augmented pressures on their caregivers, as well as a departure from the best use and hence an inefficient employment of limited resources.

Furthermore, several cancer patients have inadequate care support or may be caregivers themselves. Consequently, when **planning for the after-treatment care and support**, it is very important that the individual perspective is considered and a holistic approach is adopted. Failure to do so can have multiple undesirable consequences. One notable result is the aggravation of the "bed-blocking" problem which constantly bedevils the secondary care services. This is aggravated by the observed and forecasted increasing trends of cancer morbidity and mortality in the oldest age cohorts of the population. Figure 6 shows these trends for the proportion of patients diagnosed with cancer at age 65 years or older. This proportion is estimated to supersede 70% of all cancer diagnoses by 2030.

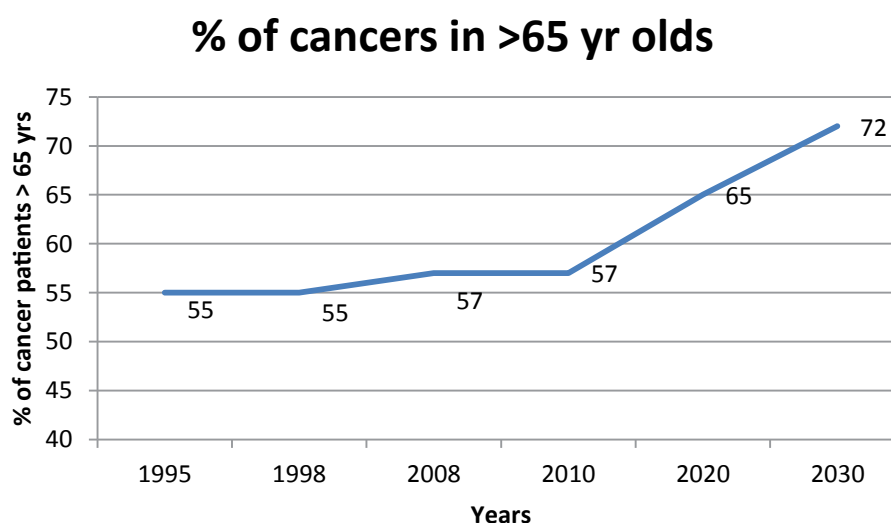


Figure 6: Proportion patients diagnosed with cancer at age 65 years of older of all cancer diagnoses.
(Source: Malta National Cancer Registry, Directorate for Health Information and Research, 2016)

Furthermore, cancer patients over the age of 65 years also have an increasing high tendency of **suffering from multiple co-morbidities including cancer**. A recent study conducted in the UK estimated that 70% of cancer patients have at least one other long-term condition that needs managing and over a quarter have at least three other such conditions (Macmillan Cancer Support, 2015). A local audit led by the Malta National Cancer Registry through the linkage of cancer registry data with data from the National Mortality Registry and the admission database at Mater Dei Hospital demonstrated comparable findings: approximately 65-67% of patients diagnosed with cancer were found to have at least one documented co-morbid condition while 22-26% were found to have records of at least three other long-term condition (National Mortality Registry, Malta, 2016 – *unpublished information*).

Cancer patients treated for a primary cancer may develop **recurrent, secondary or metastatic cancer** sometime after the end of the treatment carried out with curative intent. At this stage the patient is frequently faced with incurable disease. Nonetheless, an ever increasing proportion of these patients may be expected to live for several years with the disease. The healthcare services need to be equipped to offer the appropriate treatment and support they need to live for as long and as well as possible. Effectively this will necessitate that their cancer is managed as a chronic condition and the availability of the appropriate rehabilitation, survivorship and palliative care services on a long-term basis for an increasing proportion of cancer patients.

Notwithstanding all the cancer care services offered, for far too many patients, cancer will ultimately remain their cause of death and hence the **heightened significance of end-of-life care in the oncology sector**. Evidence from the literature shows that many of these people are not experiencing the care they would like at the end of their lives. The chances that patients' preference to die at home with the right support and with their friends and family around them is rarely possible or entertained. In Malta in 2014, only 8.7% (81 home deaths from 933 cancer deaths) of all deaths attributed to cancer took place at home. The comparable proportion for non-cancer deaths (excluding violent and accidental deaths) was 12.1% (*ibid.*). Another perennial problem is adequate pain and symptom control in the end-of-life phase. A recent study in the UK showed that just under two-thirds of those with cancer who die in a hospice have complete pain relief all the time in the last three months of life (Office for National Statistics UK, 2016).

C. ECONOMIC PERSPECTIVES: THE ECONOMIC CASE FOR CANCER CONTROL SERVICES

Cancer control is a major health care challenge. In Malta, cancer is presently accountable for nearly 30% of all deaths. Furthermore, in terms of potential life years lost, the magnitude of the problem caused by cancer is larger than that caused by heart attacks and strokes for both women and men (OECD, 2013). The **financial burden associated with cancer** is also growing and deemed to be spiralling out of control in several national health systems around the world. The ageing population resulting in an ever-increasing incidence of cancer, improving survival and high costs of emerging novel drugs and more sophisticated technologies are resulting in a powerful inflationary driver. All this dynamic activity indicates that the demand for resources and services and the growth in spending on cancer is likely to continue increasing unremittingly in the foreseeable future.

C1. Spending on cancer care at the national level

The **estimated cost of cancer** in 2014 for all the 27 countries of the EU reached €117 billion annually (€234 per EU citizen). Total costs encompassed healthcare costs (inclusive of primary and secondary healthcare), unpaid care costs by family and friends and lost income due to morbidity (such as from absence from work) and premature mortality. Healthcare costs amounted for 36% of these costs (€84 per EU citizen); lost earnings due to premature mortality and morbidity represented 36% and 8% of these costs respectively, while unpaid care accounted for the remaining 20%. However, considerable variation on the economic burden per person is known to exist across the 27 Member States (Sullivan, 2014).

In 2011, the Lancet Oncology Commission reported that the total costs of cancer care in the United States in 2010 corresponded to approximately 5% of total health care spending (Sullivan et al., 2011). An OECD review documented that in 2008, the **total spending on cancer** in England represented 5.3% of the total health spending for that year, while cancer costs in 2006 in Japan and in 2007 in the Netherlands accounted for 6.1% of the total expenditure on health (Schopper and de Wolf, 2009).

Cancer care costs are greatest during the period of initial treatment immediately following diagnosis and during the last few months before death. In 2005, a cancer patient consumed direct medical care costs of about €36,750 in the United Kingdom, 70% of which is spent in the last six months of life (Bosanquet and Sikora, 2006). At a conservative estimate, this could increase four-fold to €147,000 per patient per year by 2027 as patients live with (rather than die from) cancer and have access to new technologies. Surveys show that the majority of patients still believe that cancer care should be the highest priority and that expenditure on cancer should be far beyond that spent on any other disease.

In addition to the considerable costs of medical and social care related to cancer (Mariotto et al., 2011), the economic cost is also substantial across countries as a result of premature deaths and lost earnings (Featherstone and Whitham, 2010). Cancer causes the highest economic loss of the leading causes of death worldwide. The economic toll from cancer is nearly 20% higher than that for heart disease, the second-leading cause of economic loss (American Cancer Society, 2010). The American Cancer Society estimates that the total **economic impact of premature death and disability from cancer** worldwide (based on disability adjusted life year (DALY) and GDP per capita across countries but does not include the direct costs of treating cancer) represents 1.5% of the world's GDP. The top three cancers that cause the most economic impact globally are lung cancer, colorectal cancer and breast cancer (ibid.). Indirect costs tended to be higher when patients were below the age of 65 years.

Since cancer incidence is increasing, **medical as well as non-medical costs for cancer care are anticipated to also continue to grow** over the next 10 to 20 years. The Lancet Oncology Commission reported that in several developed countries the total spending on cancer was estimated to have grown by roughly 600% in 30 years (Sullivan, 2011).

The **level of health care spending for a particular cancer type or site is usually reflective of its prevalence and survival compared to other cancers**. Expenditure on lung cancer and colorectal cancer patients is generally higher than for breast and prostate cancer within the acute phase of care. However, total costs are known to become more similar when total lifetime costs are considered because of the difference in survival rates within and beyond the acute phase of care. An OECD report showed that due to its higher incidence and better survival, breast cancer consumes a higher level of spending (ranges between 8.3% of total cancer costs in Australia to up to 19.0% in Denmark) compared to 8.1% and 13.6% respectively on colorectal cancer. On the other hand, spending was generally lower on less favourable cancers in terms of survival such as for lung cancer: range was between 4.7% and 11.2% of total cancer costs (Schopper and de Wolf, 2009).

C2. Spending on cancer care at the individual level

Despite the concerns of many about how and who will pay for such escalating costs at the national or healthcare providers' level, the problem is even worse from the **economic perspective of the patient, family, and society**. Cancer patients and their carers also bear significant costs, both financial and social. Apart from medical care costs, **cancer patients also incur expenses on non-medical care**. This expenditure places an added burden on them and their caregivers. The annual cost of the informal care provided by family and friends in the first year after diagnosis was estimated to reach 21% of the medical costs in a group of breast cancer patients studied in Sweden (Lidgren et al., 2007).

In addition, there are indirect costs associated with the morbidity of cancer care such as **days lost from work for the patient or caregiver**. Hospitalization represents approximately two-thirds of the estimated time costs. Non-medical costs were found to approach as much as half the direct medical costs during the terminal phase of illness with hospitalization representing the single largest contribution (Lyman, 2007). **Intangible costs** such as pain and suffering and loss of companionship are difficult to measure but very real to the patient and family. Unfortunately, the economic value of nonmedical costs such as time required to obtain care or indirect and out-of-pocket expenses or loss of work productivity, are rarely considered (ibid.).

Patients also face substantial economic burden post-cancer treatment due to a number of **treatment-related health problems**. A study done on breast cancer patients showed that more than 90 % of women experienced at least one adverse effect (i.e., post-surgical issue, reaction to radiotherapy, upper-body symptoms or reduced function, lymphoedema, fatigue, or weight gain). Women with any one of the following symptoms (fatigue, reduced upper-body function, upper-body symptoms) or women who reported four or more adverse treatment-related effects, had 1.5 to nearly 4 times the odds of having higher healthcare costs than women who did not report these complaints ($p < 0.05$). These health related problems might persist beyond the treatment period. Improving cancer care by investing in surveillance of treatment-related side effects and strategies for prevention and treatment of concerns (e.g., exercise) could reduce patient-borne costs (Schmitz et al., 2014).

C3. Economic implications for different stages in the cancer care pathway

Cancer control services involve several different professionals, resources and set-ups and national authorities need to make sure that they provide effective, high quality cancer services throughout the cancer patient pathways.

Prevention is an important and valuable intervention for cancer control, reducing risk factors and delaying the onset of disease. Early diagnosis and timely evidence-based care are critical for patients during the phases of recovering from and living with cancer, and improves survival. In addition, more effort needs to be invested within the cancer care systems as well as the labour markets to ameliorate the quality of life of cancer survivors and of patients and their caregivers.

C3.1 Promoting prevention and early diagnosis

Several **prevention policies** have been introduced and implemented to help avoid and delay the onset of cancer, but further efforts can be made to improve life styles and decrease cancer incidence. For example, smoking rates are being successfully reduced through anti-smoking policy measures (smoking being responsible for 20% of all cancer deaths), but additional efforts need to be made to effect well-established risk factors for cancer such as obesity, as one-third of cancers are still considered preventable (Koutsokera et al., 2013). Diet and physical-activity related factors account for 20-25% of cancer cases (World Cancer Research Fund International, 2014). OECD analyses showed that implementing resource appropriate prevention packages to improve diets, increase physical activity and tackle obesity in Europe would, after the initial 10 years lead to gains of over 3 million years of life free of cancer and after a further 10 years, gains in cancer-free life years would reach to 11.8 million (Cecchini et al., 2010).

Furthermore, the drop in labour force participation attributable to cancer has been estimated at 10% and approximately 36% of employees do not return to work following cancer treatment (Bradley, Bednarek and Neumark, 2002). This highlights the importance of prevention of and protection from occupational and environmental cancer risks and the effectiveness of work-place health promotion programs (Baicker, Cutler and Song, 2010).

A decisive factor that is essential to register improvements in the chances that cancer patients successfully survive cancer is **early diagnosis and rapid referral for the start of the required therapies**, frequently surgery and oncological treatments. Several countries have successfully implemented **nationwide population-based screening programmes** for breast, colorectal and cervical cancers in the past few years. Screening should be offered only if it proves to reduce mortality, cost-effectiveness is acceptable, high quality assurance standards are achieved and maintained and every effort expended to involve and educate the public and to assume their role as the primary producers of their own health (European Union, 2003).

Studies have shown that management of breast cancer diagnosed at a late stage of the disease (stage III and IV) is three times more expensive compared to the management of breast cancer detected and confirmed at the earlier stages (stage I and II) (Union for International Cancer Control, 2014). Population-based colorectal cancer screening has been also confirmed to be either more cost-effective or cost-saving compared to no screening. Likewise, the incidence of cancer of the cervix can be substantially prevented and reduced on a national scale with the combination of vaccination against Human Papilloma Virus (HPV) and cervical cancer screening programs (European Union, 2003).

C3.2 Enhancing evidence-based and timely delivery of cancer care

Cancer care costs are greatest during the period of initial treatment immediately following diagnosis and during the last few months before death. The cancer care offered to patients should be based on evidence and current best practice in a multi-disciplinary setting, without exception. Additionally, every effort should be employed **to reduce the likelihood of unacceptable variations in care standards or processes** such as through the development, implementation and monitoring such as for level of compliance of national clinical guidelines around the management of the most common cancers (OECD, 2013). Studies in several countries have shown that variations in medical practice lead to differences in cancer outcomes and that cancer survival was related to the delivery of care. Survival from rectal cancer differed by 5-10% between hospitals in the Netherlands due to differing quality standards of the healthcare providers while in Hungary the existence of known perverse incentives resulting in increases in the surgeon's income if surgery is performed lead to breast cancer patients undergoing surgery even when clinical guidelines recommend otherwise (OECD, 2013). The delivery and promotion of high-quality cancer care is further ensured by the implementation of several initiatives including the availability of feedback mechanisms for service providers, the monitoring and reporting of the effectiveness of cancer care interventions and benchmarking with international clinical standards.

Following diagnosis, patients need to access **high-quality care in a timely manner**. Waiting times to see a cancer specialist and to start surgical, radiotherapy, chemotherapy or combination treatment should be minimised, but variations persist within and across countries. Significant socio-economic differences in cancer survival have been shown to be related to differences in access and waiting times (Verdecchia et al., 2007), (Lejeune et al., 2010). Longer waiting times are linked with poorer cancer survival and they can be caused by several factors including shortages of and unequal distribution of resources and inefficient referral systems (OECD, 2013). Waiting times can be tackled through the employment of multi-pronged approaches such as improving care co-ordination, streamlining care delivery and also increasing resources, such as medical devices, healthcare workforce and facilities for cancer care. Additionally, the systematic measurement of waiting times is essential to effectively reduce waiting times, and international benchmarking in this area has also been shown to be valuable. Several countries are in the process of introducing maximum waiting time guarantees and fast-track pathways for several cancer sites.

C3.3 Supporting labour market activities and providing services to improve quality of life of patients and carers

Similar to any other patients require continued health care, **cancer patients frequently confront the risk of losing their jobs and of reduced working hours during and after treatment**. Studies have confirmed that the likelihood that cancer survivors are working after treatment is lower than that of their age cohorts that have not experienced cancer (Bradley et al., 2005). Furthermore, working survivors also report reductions in wages, in working hours and in opportunities for promotion (Ahn et al., 2009). The necessity to apply measures to utilise the active participation by cancer patients and survivors who are willing to take part in labour market activities is accentuated by the demographic explosion of population-ageing which is leading to a substantial shrinking labour force populations and the expected increase in cancer incidence in the coming years. Introducing and upgrading measures to support cancer patients and survivors, such as facilitating the uptake of sick leave and disability assistance and the supply of adequate services for psychological support and counselling are critical to improving labour market outcomes (Carlsen et al., 2008).

The **provision of high-quality palliative care and end-of-life services** in different settings including at the patients' homes, in hospices, nursing homes and specialised palliative institutions together with services that help alleviate and improve the quality of life of the families and other caregivers of cancer patients are challenges that need to be tackled sensitively and comprehensively. Studies have shown that hospital-based palliative care consultations can reduce hospital costs by up to USD 7,500 for patients that die during their last admission (Morrison et al., 2011). Similarly, home-based palliative care can reduce the overall cost of care by up to USD 7,500 per cancer patient (Enguidanos, Cherin and Brumley, 2005).

Caring for cancer patients can be very demanding. A study performed in Canada substantiated this statement by showing that 5% of informal caregivers of breast cancer patients had quit their jobs or declined a promotion (Grunfeld, 2004). Various labour market and tax policies have been employed in different countries to address these concerns and include paid leave, flexible work schedules, tax credits and exemptions and income supplements (Marchildon, 2005).

In conclusion, we have due reason to celebrate several achievements following the publication of the first National Cancer Plan for Malta in 2011. Examples include the introduction of the three population-based cancer screening programmes and the HPV vaccination programme and the opening of the brand new Oncology Centre which is housing updated treating equipment and expanded services. However, it is being acknowledged that there remains much more that needs to be done. The new National Cancer Plan (2017 – 2021) is aiming to address pending and emerging new challenges in cancer prevention and cancer care.

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CHAPTER 2

REDUCING GROWTH IN THE NUMBER OF CANCER CASES

1.0 INTRODUCTION

More than one-third of all cancer cases are preventable and cancer prevention, especially when integrated with prevention of chronic diseases offers the most cost-effective long-term strategy for the control of cancer (World Health Organisation, 2013).

An estimated 4 out of 10 cases of cancer could be prevented, mostly through modifiable aspects of our lifestyles. Tobacco use, and particularly cigarette smoking, is the single most important and best known avoidable cause of cancer in the European Union (EU) (Leon et al., 2015). It was found to be responsible for up to 20% of all new cancer cases. The relative importance of other exposures frequently differs by gender. In men, deficient intake of fruits and vegetables (6.1%), occupational exposures to carcinogens (4.9%) and alcohol consumption (4.6%) follow tobacco in importance. On the other hand, in women, overweight and obesity (because of their effect on breast cancer) was responsible for 6.9% of cancers, followed by 3.7% with respect to infectious agents (with 100% responsibility for cancer of the cervix of the uterus) (Parkin, Boyd and Walker, 2011). Other known risk factors include UV exposure, lack of sufficient physical activity, exposure to various infectious agents and carcinogens in the environment (notably in the air, water and food), and radiation.

There is much more that we can do to ensure that people are engaging with service providers early enough so that focus is shifted more onto prevention rather than on diagnosis and treatment of disease. The health services will not be able to sustain comprehensive health and social care coverage unless more nation-wide (whole-of-government) and inter-sectoral (whole-of society) concerted actions on prevention are adopted, supported and implemented so that real health outcomes are achieved (Kickbusch, 2013). A fundamental transformation is required to reset the social contract within society, such that individuals are motivated and empowered to take more responsibility for their own health.

The European Health Interview Survey that was conducted in Malta in 2014 showed that nearly one in five adults described themselves as regular smokers and a third of the population reported that they drink alcohol on a weekly or more frequent basis. Furthermore, only a third of the adults interviewed stated that they perform physical activity for 150 minutes or more per week, while three out of five adults are overweight or obese. All these figures demonstrate that there is a huge scope for increasing the effort and investment needed to plan, implement and evaluate various measures so that the health status of the population improves and to ensure that preventable cancer risks are positively affected and can be shown to abate over the term of this National Cancer Plan.

The impact of several of the preventable cancer risks can be diminished through:

- health promotion and disease prevention focused on healthy public policies,
- the creation of supportive environments,
- the strengthening of community actions,
- the development of personal skills, and
- the reorientation of the focus of health services towards more prevention to achieve and maintain optimal impact (Sepúlveda, 2006).

1.1 Lifestyle choices

The four main strands that need to be pursued to prevent cancer through healthy lifestyle changes and choices are:

1. Continued education and awareness activities especially targeting high-risk groups in order to achieve the most impact and favour health equity
2. Strengthened enforcement of legislation and regulations that restrict and control access and exposure to harmful products and environments
3. Creating supportive environments and strengthening community actions and whole-of-society commitment
4. Supporting individuals to bring about and sustain lifestyle changes and healthy choices (Martin-Moreno, 2015).

Awareness needs to start early and be sustained throughout the whole life-course, in various settings and at every possible encounter especially with the health services. Each time a person interacts with the health services is an opportunity to encourage a conversation about healthy lifestyles. Making 'every contact count' is an essential culture shift that needs to be embraced by everyone involved in the health services and has contact with patients and their carers and the public. Early awareness would provide young people with the confidence to make better use of primary care services in later life and to be able to have constructive conversations about their health and therefore the progression of children through school presents an opportunity to influence both the child's as well as his/her family's, lifestyle behaviours. Furthermore, inviting and encouraging attendance to the Lifestyle clinics that are spreading to all parts of the Islands offer an excellent opportunity for members of the public to assess their health status and to learn how and be supported to improve their personal well-being with healthier lifestyle choices.

These objectives will be reached through:

1. Increasing awareness and concentrating and reinforcing programs aimed at selected vulnerable groups and high risk lifestyles. Selected vulnerable groups will include:

- i. children
- ii. youth and young adults
- iii. people with high risk life behaviours/ choices (e.g. smokers, high alcohol consumption, high body mass index)
- iv. people working in high risk occupational settings (e.g. sex workers, workers in the hospitality industry, certain manufacturing and other industries)
- v. groups exposed to socio-economic pressures.

Ongoing weight management classes, diabetic weight management classes, self- management classes and tobacco cessation services will be strengthened and expanded to reach more people.

2. Designing and implementing communication campaigns that are tailored to different media and audiences with the aim of raising awareness on different risk factors for cancer (including smoking, alcohol, diet and nutrition, physical inactivity, UV rays, unprotected sex, carcinogens in the home, environment and workplace). These programmes with cancer-related communications will complement and support other disease prevention messages and campaigns.
3. The celebration of events that give visibility to cancer prevention, such as World No Tobacco Day, the European Week Against Cancer, World Cancer Day, Breast Cancer and Colon Cancer Awareness Months. Cancer prevention messages will also be included in the celebration of other thematic events such as World Obesity Day, Move for Health Day, World Oral Health Day.
4. The conduction of life skills-based health promotion programmes/seminars in schools, workplaces and for local community leaders.
5. The dissemination of the European Code against Cancer (IARC) in schools, workplaces, health and community centres.
6. Continuing the conduction and promotion of vaccination programmes
7. Strengthened enforcement and monitoring of relevant legislation and regulations, including:
 - i. tobacco control legislation
 - ii. alcohol control legislation
 - iii. environment control and protection legislation
 - iv. occupational Health and Safety (OHS) legislation
 - v. protection from UV radiation exposure
8. Introducing explicit funding and support for cancer epidemiology, Public Health research in the field of prevention, the identification of groups with higher risks in order to inform the prioritisation of targeted action and for the ongoing monitoring and evaluation of health promotion programmes.

1.2 The European Code against Cancer

The European Code against Cancer (ECAC) is a series of prevention messages and guidelines targeting all EU citizens developed by committees of experts commissioned by the European Union in collaboration with the International Agency for Research on Cancer (IARC). The first version of ECAC was published in 1988 and the fourth edition was launched in 2015 (Harpal, 2015). The aim of these recommendations are to inform people about actions they can take for themselves or their families to reduce their risk of cancer. The current version comprises of twelve (12) recommendations that most people can follow without any special skills or advice.

1. Do not smoke. Do not use any form of tobacco.
2. Make your home smoke free. Support smoke-free policies in your workplace.
3. Take action to be a healthy body weight.
4. Be physically active in everyday life. Limit the time you spend sitting.
5. Have a healthy diet:
 - Eat plenty of whole grains, pulses, vegetables and fruits.
 - Limit high-calorie foods (foods high in sugar or fat) and avoid sugary drinks.
 - Avoid processed meat; limit red meat and foods high in salt.
6. If you drink alcohol of any type, limit your intake. Not drinking alcohol is better for cancer prevention.
7. Avoid too much sun, especially for children. Use sun protection. Do not use sunbeds.
8. In the workplace, protect yourself against cancer-causing substances by following health and safety instructions.
9. Find out if you are exposed to radiation from naturally high radon levels in your home. Take action to reduce high radon levels.
10. For women:
 - Breastfeeding reduces the mother's cancer risk. If you can, breastfeed your baby.
 - Hormone replacement therapy (HRT) increases the risk of certain cancers.
 - Limit use of HRT.
11. Ensure your children take part in vaccination programmes for:
 - Hepatitis B (for newborns)
 - Human papillomavirus (HPV) (for girls).
12. Take part in organised cancer screening programmes for:
 - Bowel cancer (men and women)
 - Breast cancer (women)
 - Cervical cancer (women).



Figure 7: European Code against Cancer – 12 ways to reduce your cancer risk

1.3 Smoking

Tobacco smoking is the most significant preventable cause of cancer. Over 8,000 compounds have been identified in tobacco and tobacco smoke and these include more than 70 carcinogens classified by the IARC because sufficient evidence has been accrued that demonstrates carcinogenicity in either laboratory animals or humans (Rodgman and Perfetti, 2013). Several of these carcinogens have been linked to the multiple cancers which occur in tobacco users and non-smokers exposed to second-hand smoke (Hecht and Szabo, 2014).

Table 2 shows the trend of the proportion of the population that are regular smokers, by gender from 2002 to 2014. When self-reported occasional smokers are also added, the proportion of female smokers in 2014 rises to 20.9% and the corresponding proportion for males reaches 27.8%. These results equate to more than 100,000 active adult smokers. It has been shown that two-thirds of long-term smokers will die as a result of their smoking if they do not quit this unhealthy behaviour and that on average cigarette smokers die ten years younger than non-smokers (Doll et al., 2005).

	National Health Interview Survey 2002	European Health Interview Survey 2008	European Health Interview Survey 2014
Women	17.6%	15.8%	17.2%
Men	29.9%	25.6%	23.6%
Both genders	23.4%	20.4%	20.3%

Table 2: Percentage of self-reported regular smokers (aged 16 and over) in Maltese residents by gender.

Source: National Health Interview Surveys – 2002, 2008, 2014, Directorate for Health Information and Research, Ministry for Health, Malta

Furthermore, smoking prevalence is highest in people from lower socio-economic levels. Table 3 shows that the percentage of self-reported regular smokers (aged 16 and over) in Maltese residents in 2014, reached 23.2% for people that completed a primary level of education or less and decreased to 12.5% in persons who had completed a tertiary level of education.

	European Health Interview Survey 2014
ED0-2 [No education to lower secondary education]	23.2%
ED3-4 [Upper secondary education to post-secondary non-tertiary education]	18.7%
ED5-8 [Tertiary education]	12.5%
Total [all ISCED levels combined]	20.3%

Table 3: Percentage of self-reported regular smokers (aged 16 and over) in Maltese residents classified according to the international Standard Classification of Education (ISCED) categories (UNESCO Institute of Statistics).

Source: National Health Interview Surveys – 2002, 2008, 2014, Directorate for Health Information and Research, Ministry for Health, Malta

Smoking remains the leading cause of preventable death and disease. It was responsible for 13.3% of all deaths in adults aged 30 and over in 2015. Apart from its impact on cancer risk, there is also growing evidence that smoking also has a substantial impact on the response to treatment (Leon et al., 2015). Tables 4 and 5 show mortality attributable to females and males in Malta in 2005 and 2015 respectively¹. These tables show that while the mortality attributable to tobacco rates remained relatively stable in men, a marked increase was registered for women in 2015 compared to the situation for 2005.

2005	Females					
Age group	30-44	45-59	60-69	70-79	80 and over	Total for ages 30 and over
number of deaths from all causes (ICD 10: A00-Q99)	18.00	116.00	167.00	373.00	793.00	1467.00
number of deaths attributable to tobacco	0.00	10.82	6.54	9.42	0.00	26.79
Death rate attributable to tobacco per 100,000	0.00	24.06	32.59	65.45	0.00	21.24
Proportion of deaths attributable to tobacco (%)	0.00	9.33	3.92	2.53	0.00	1.83
2015	Females					
Age group	30-44	45-59	60-69	70-79	80 and over	Total for ages 30 and over
number of deaths from all causes (ICD 10: A00-Q99)	13.00	84.00	191.00	329.00	1028.00	1645.00
number of deaths attributable to tobacco	0.00	18.05	13.27	25.83	31.46	88.62
Death rate attributable to tobacco per 100,000	0.00	43.18	44.65	140.58	281.56	61.12
Proportion of deaths attributable to tobacco (%)	0.00	21.49	6.95	7.85	3.06	5.39

Table 4: Mortality attributable to tobacco in women in Malta in 2005 and 2015

Source: National Mortality Registry, Directorate for Health Information and Research, Ministry for Health (2016).

1. The method used to calculate mortality attributable to tobacco is based on the Population Attributable Fraction Method used in the WHO Global Report: mortality attributable to tobacco (2012).

2005	Males					
Age group	30-44	45-59	60-69	70-79	80 and over	Total for ages 30 and over
number of deaths from all causes (ICD 10: A00-Q99)	18.00	155.00	255.00	482.00	560.00	1470.00
number of deaths attributable to tobacco	0.00	21.48	69.15	130.28	73.43	294.34
Death rate attributable to tobacco per 100,000	0.00	47.99	385.42	1260.00	1682.32	249.11
Proportion of deaths attributable to tobacco (%)	0.00	13.86	27.12	27.03	13.11	20.02

2015	Males					
Age group	30-44	45-59	60-69	70-79	80 and over	Total for ages 30 and over
number of deaths from all causes (ICD 10: A00-Q99)	24.00	133.00	330.00	425.00	711.00	1623.00
number of deaths attributable to tobacco	8.34	36.17	86.69	100.66	113.64	345.50
Death rate attributable to tobacco per 100,000	17.76	85.10	301.37	652.58	1793.56	246.83
Proportion of deaths attributable to tobacco (%)	34.73	27.20	26.27	23.68	15.98	21.29

Table 5: Mortality attributable to tobacco in men in Malta in 2005 and 2015

Source: National Mortality Registry, Directorate for Health Information and Research, Ministry for Health (2016).

Health inequalities are preventable differences in health outcomes between different population groups. It has been shown that smoking behaviour is the single most important driver of health inequalities, that variances in the smoking prevalence across the population induce major differences in death rates and illness, and that people in the lower socio-economic groups tend to consistently start smoking earlier are heavier smokers and smoke for longer periods than people in the managerial and professional categories (Rodgman and Perfetti, 2013). Measures aimed at reducing health inequalities can have a greater effect on smokers in the higher prevalence groups and in practice, this translates into both prioritising targeting interventions towards these smokers and designing and implementing population-level interventions which are more attractive and accessible to smokers in high risk groups (ASH briefing: *Health inequalities and smoking*, 2016).

A special population that needs augmented attention during the time span of this Plan are persons with mental health problems. Research in the US showed that the annual average smoking prevalence of current smokers in adults with mental illness reached 36.1% during 2009-2011 (compared to 21.4% among adults with no mental illness), that they smoke more frequently and heavily than the general population and that they may encounter greater obstacles to access smoking cessation services (Centres of Disease Control and Prevention, 2013).

The focus of this Plan is to maintain and strengthen the drive to continue the decline in smoking rates. This objective will be reached through:

- 1. Preparation and publication of a new Tobacco Control Strategy by the Committee on Smoking and Health to reinforce the activity to maintain and strengthen reductions in:**
 - i. smoking rates in adults (with a special focus on women)
 - ii. smoking rates in selected high risk groups, such as pregnant women, persons with mental health problems, high risk occupational settings, children and youth. Targeted measurement of the smoking prevalence within these identified high risk vulnerable groups will be planned and conducted
 - iii. the take-up rate of smoking in adolescents
 - iv. the exposure of non-smokers to second-hand smoke (passive smoking)
- 2. Implementation, monitoring and enforcement of enacted and pending directives. These include the full implementation of the World Health Organisation Framework Convention on Tobacco Control (WHO FCTC) on actions by Customs on illicit trade. Special and augmented attention will be given to:**
 - i. protection of people from tobacco smoke in public places and work places, and open spaces frequented by children
 - ii. monitoring and enforcement of existing smoking bans in healthcare facilities
 - iii. creation and implementation of an anti-smoking policy in mental health institutions
 - iv. continuing to increase awareness on the dangers of passive smoking especially for children and young people
 - v. enforce applicable restrictions and bans on tobacco advertising, promotion and sponsorship and applicable penalties on transgressions of the law
 - vi. ensure that effective measures are taken to minimise the entry into Malta of illicit and therefore cheaper tobacco products
- 3. Continue to augment capacity and quality of services supporting smoking cessation.**
- 4. Regularly continue with the increases in the taxes imposed on the sale of tobacco products.**

1.4 Alcohol consumption

The consumption of alcoholic beverages has been shown to be related to increases in the cancer risk in humans especially in the occurrence of malignant tumours of the oral cavity, pharynx, larynx, oesophagus and liver. The risk has been found to be dose-related with increasing risk associated with higher volumes of daily intake of alcohol (Parkin, 2011), (Scoccianti et al., 2015). Apart from increasing the risk for cancer, alcohol intake is also strongly associated with increased risk for other health conditions. The general awareness of the links between alcohol and cancer risk is low and therefore, this presents an opportunity for a comprehensive alcohol strategy to acknowledge the risk of cancer and consequently to help drive behaviour change accordingly.

Actions to achieve gains in this area will be congruent with and aim to support measures included in the upcoming National Alcohol Policy. Measures will aim at:

1. Strengthening inter-sectoral collaboration with the National Agency leading this National Alcohol Policy.
2. Planning and conducting training for health care providers in primary care and Admission and Emergency services and facilities to identify persons with hazardous and harmful patterns of alcohol consumption by using tools such as the Alcohol Use Disorders Identification Test (AUDIT) promoted by WHO (Babor et al., 2001).
3. Strengthening and reinforcing awareness of the risks of alcohol consumption for pregnant women, their partners and their babies during parent-craft classes.
4. Working with employers (particularly for large businesses) to promote the introduction of alcohol policies within workplaces with the aim of promoting more awareness, early intervention and support for employees.

1.5 Nutrition and Diet, Weight Control and Physical Activity

The report of the World Cancer Research Fund (WCRF) Panel on Food, Nutrition, Physical Activity, and the Prevention of Cancer issued in 2007 claimed that there was convincing evidence for an association of overweight and obesity with cancers of the pancreas, colon and rectum. This claim re-affirmed an earlier assertion made in the IARC Handbook on Weight Control and Physical Activity (2002a) which had also concluded that there is an association with increased risks for cancers of the endometrium, kidney, oesophagus and post-menopausal breast cancer. This list of cancers has been deemed to be a conservative one and several other and more recent studies have identified an increased risk for a large number of other cancers associated with excess body mass (Parkin and Boyd, 2011).

The health impact of excess body weight and the related attitudes and behaviours leading to unhealthy dietary practices and insufficient physical activity have been acknowledged as critical challenges for the health of the population. The significance of these parameters is continuously growing as our national performance is repeatedly demonstrating undesirable results as demonstrated in Table 6 below.

	National Health Interview Survey 2002	European Health Interview Survey 2008	European Health Interview Survey 2014
Overweight BMI: 25-29.9 kg/m ²	34.3%	36.2%	34.4%
Obese BMI: ≥30 kg/m ²	23.1%	22.4%	25.3%

Table 6: Percentage of overweight and obese persons in the population. Body Mass Index (BMI) calculated from self-reported weight and height (aged 16 and over) in Maltese residents.

Source: National Health Interview Surveys – 2002, 2008, 2014, Directorate for Health Information and Research, Ministry for Health, Malta.

Actions to achieve gains included in the National Cancer Plan are congruent with and will support the implementation of measures included in the Food and Nutrition Policy and Action Plan (FNAP, 2014) and the Healthy Weight for Life Strategy (HWL, 2012). The implementation of these two national strategies is led by the Health Promotion and Disease Prevention Directorate. Special attention will be devoted to the following measures:

1. Introduction of legislation to uphold the implementation of dietary guidelines for institutions and workplace canteens and include a requirement for healthy options such as vegetables and fruit.
2. Ensure food supplied in schools is in line with healthy eating as outlined in the Whole of School approach to healthy lifestyles (2015).
3. Introduction of restrictions on the marketing of sweets, soft drinks and other fatty and sweet foods (foods high in fat, sugar and salt). This activity will be supported by the Audio-Visual Directive which is currently being discussed at the EU level.
4. Strengthen the uptake of health enhancing physical activity. This work will be accomplished through intersectoral collaboration within the Advisory Council on Healthy Lifestyles. A major aim of this measure will be the finalisation and implementation of activities promoting, facilitating and delivering a Health Enhancing Physical Activity Strategy throughout the life span and in all settings.
5. Promote the creation of safe public spaces which encourage physical activity in everyday activities through consultation with relevant stakeholders including at local council level.
6. Conduct regular food consumption surveys to monitor the eating habits of the population and to guide actions for food product improvement and effective educational campaigns.

1.6 Solar ultraviolet (UV) Radiation Exposure

Sun exposure is related to three main types of skin cancer. Basal cell carcinoma is the most common type of skin cancer but its severity is usually limited since this tumour is localized at skin level. Squamous cell carcinoma exhibits the clearest relationship with cumulative sun exposure. It is the commonest form of skin cancer among people who regularly work outdoors. There is evidence that the third type of cancer (and the most serious one in terms of prognosis), cutaneous melanoma, is related to intermittent sun exposure such as sunbathing and outdoor sports. A history of sunburn has also been repeatedly described as a risk factor. Globally, over the last three decades, the incidence rates for cutaneous melanoma have escalated at faster rates than those for any other malignancy in Caucasian populations and other fair-skinned people and mortality rates have continued to rise notwithstanding ameliorating survival rates over this period (Giblin and Thomas, 2007). Squamous and basal cell carcinomas account for 95% of all skin cancers and although they are significantly less life-threatening than melanoma, their management result in a considerable burden at both the levels of the individuals involved and the healthcare systems (Coleman et al., 2008).

Sun-beds, sunlamps and tanning booths emit the same type of hazardous radiation as sunlight. Sun-beds often give out larger doses of UV radiation than the midday tropical sun. The UV rays emitted by sun-beds increase the cancer risk for skin cancers (both malignant melanoma and non-melanoma). The risks are greater for young people and evidence shows that persons that are frequently exposed to UV rays before the age of 25 years and who have experienced repeated bouts of sunburn in childhood have a significantly greater risk of developing skin cancer later in life (Green et al., 2006).

This Plan will address this important risk factor through:

- 1. Maintaining and upgrading annual sun awareness campaigns by continuing to strengthen the inter-departmental collaboration and support of the relevant industry to sustain annual sun awareness campaigns for the general population.**
- 2. Undertaking a baseline national study to ascertain the knowledge, attitudes and behaviour of the population living in Malta with regards to sun awareness and exposure to natural and artificial ultraviolet radiation through the use of indoor tanning facilities.**

1.7 Infectious agents that can cause cancer

It is estimated that between 15-20% of human malignancies worldwide are attributable to persistent infections with bacteria, viruses or parasites. The percentage estimated for the EU region is lower (10%), with the most marked impact demonstrated on the incidence of cancers of the cervix uteri, liver and stomach, and a number of malignancies of the blood-forming (haematological) or lymphatic systems (Lawn and Campion, 2013).

Viruses that are now known or suspected of being linked to cancer in humans include Human Papilloma viruses (HPV), the Epstein-Barr virus (EBV), the hepatitis B and C viruses (HBV and HCV), the Kaposi Sarcoma-associated Herpesvirus or human herpes virus 8 (KSHV, HHV-8) and the human T-lymphotrophic virus-1 (HTLV-1) (University of Wisconsin, 2011). The latter has been linked to a type of lymphocytic leukaemia and non-Hodgkin lymphoma called adult T-cell leukaemia/lymphoma. EBV is associated with around 15% of cancers of the stomach cancers, most nasopharyngeal cancers (cancer of the nasopharynx, the region behind the nose and above the back of the throat), and certain types of lymphomas. Globally, a high percentage of liver cancers are caused by long-term infections with HBV and HCV.

The causal role of the Human Papilloma Virus (HPV) in cervical cancer has been well established with several viral sub-types being earmarked as oncogenic viruses. Virtually all cases of cervical cancer are caused by HPV infections. Furthermore, it has been estimated that approximately 5% of all cancers worldwide are caused by oncogenic HPV and these include cancers of the anus (implicated in 95% of cases), 70% of all cases of cancers of the oropharynx (cancers of the middle part of the throat, including the soft palate, the base of the tongue, and the tonsils), and high proportions of cancers of the vulva, vagina and penis (National Institute of Health, 2015).

Human immunodeficiency virus (HIV), the virus that causes acquired immune deficiency syndrome (AIDS), has not been directly shown to cause cancers. However, infection with HIV increases a person's risk of getting several types of cancer, especially some linked to other viruses. This is believed to be related to the weakening of the immune system resulting from an infection with HIV.

Helicobacter pylori bacterial infection is associated with a marked increased risk for cancer of the stomach and it is estimated that about almost two thirds of new cases of gastric cancer each year in the EU may be attributable to bacterial infection. Finally, certain parasitic worms that can live inside the human body can also raise the risk of developing some kinds of cancer such as liver flukes that occur mostly in East Asia and have been linked to an increased risk of developing cancer of the bile ducts and a water parasite found in the Middle East, Africa and Asia which can cause Schistosomiasis and has been associated with cancers of the urinary bladder. Cancer risks caused by these parasites can be of concern to health systems as they can be imported by people who originate from, live in or travel to these parts of the world (American Cancer Society, 2016).

Actions included within this Plan to address the cancer risks posed by infectious agents include:

1. The consolidation of the HPV vaccination programme. An evaluation of the programme will be performed at the completion of the first 5 years. This will include an exploration of the impact of expanding the program to include male children of the same age cohort of the girls already being invited. The HPV vaccine can help prevent boys from getting infected with the types of HPV that can cause cancers of the mouth/throat, penis and anus. The vaccine can also help prevent genital warts. HPV vaccination of males is also likely to benefit females by reducing the spread of HPV viruses (Centre of Disease Control and Prevention, 2015), (European Centre for Disease Control, 2014).
2. Monitor and maintain high population HBV vaccination levels. Special attention will be given to assess and sustain outreach activity to vulnerable segments of the population and maintain these target based programs.
3. Support and assist the implementation of the Communicable Disease Strategy (Infectious Disease Prevention and Control Unit, 2013). Introduce procedures to regularly monitor and screen patients with a higher risk for cancer because of all the above-mention infective agents for early signs and symptoms of developing neoplastic disease.

1.8 Occupational and environmental factors – risks and opportunities for prevention

Throughout their lifespan people come in contact with a wide variety of environmental and occupational pollutants from different sources in their home, at their workplaces or in the general environment. Most of these exposures are not normally within the direct control of the individual person and include exposure to several chemicals, metals (such as chromium, nickel and cadmium), dusts (such as silica and wood dust), and fibres (such as asbestos). Contact with pollutants from different sources takes place through different pathways and exposure routes (such as inhalation, ingestion or skin contact). Some exposures are widespread (e.g. air pollution, food and water contamination), while others are limited to small or circumscribed areas, such as, specific occupational settings and industrial sites. Environmental exposures may be more hazardous during gestation and more in children than in adults and that environmental or occupational exposures during the peri-conception phase and pregnancy may increase the risk of cancer in the offspring (Bailey et al., 2014), (Togawa et al., 2016).

A number of these exposures have been established to be causally associated with an increased risk for specific cancers, such as cancers of the lung, skin and urinary bladder, and mesothelioma (Espina et al., 2015). However, despite the numerous established associations, it needs to be acknowledged that the scientific knowledge of the carcinogenic potential of several occupational and environmental chemicals is still inadequate, and therefore unremitting re-evaluation of the evidence for most implicated occupational and environmental chemicals is crucial (Giblin and Thomas, 2007).

1.8.1 Occupational factors

A study conducted in Great Britain estimated that 5.3% of the total cancer deaths and 4.0% of all cancer registrations were attributable to occupational exposures and circumstances in 2005 and 2004, respectively (Rushton et al., 2012). Furthermore, for male workers, exposures to cancer causing agents in the workplace was ranked to be the fifth most important contributor to preventable cancer cases in Great Britain after tobacco, diet, obesity and alcohol (Parkin, Boyd and Walker, 2011). However, in common with most work-related ill-health, it is highly likely that the importance of exposure to carcinogenic risk factors in occupational work settings is underestimated and undervalued (Siemiatycki et al., 2004).

Chemical substances and radiation are well-known causes of occupational cancer. Nevertheless, only a relatively small number of cancer-causing chemical exposures have been to date thoroughly investigated, whilst there is a growing acknowledgment that other identified cancer-related risks, such as physical, pharmaceutical and biological factors, require intensive and ongoing study (Lišner et al., 2014). Occupational exposures have been most frequently connected to malignant neoplasms of the lung, urinary bladder, liver, larynx and nasopharynx, nose and nasal cavity, mesothelioma, leukaemia, and non-melanoma skin cancers. Several other malignant tumours have also been linked with occupational exposures, but existing evidence is still classified as insufficient (Coleman et al., 2008). Furthermore, there is substantial evidence of increased risks associated with specific industries and occupations, although frequently no specific agents can be recognised as the principal aetiological factor. Common occupational exposures include solar radiation, passive smoking, crystalline silica, diesel exhausts, radon, wood dust, benzene, asbestos, formaldehyde, polycyclic aromatic hydrocarbons, chromium (VI), cadmium and nickel compounds. Finally, occupational risk is rarely the result of exposure to a solitary factor and it is acknowledged that combinations of factors are frequently implicated (Siemiatycki et al., 2004).

Knowledge generated and contributed from research needs to be translated into prevention measures and legal requirements by legislators and regulators. During the time span of this Plan, measures will be taken that at the national level that will focus on the following two main objectives:

1. Improve the monitoring of occupational exposure to carcinogens and cancer-related working conditions (Lišner et al., 2014). This aim will be reached through:

- i. **Introducing and enforcing legally binding reporting of occupational disease (including cancers)**
- ii. **Upgrading the current reporting system to be in line with and guided by the relevant EU Directives and the parallel legal provisions as transposed into the Maltese Legislation.**
- iii. **Planning and conducting training programs and campaigns aimed at the relevant actors and the general public to raise the awareness and knowledge on occupational risks and diseases vis-à-vis the risk for cancers.**
- iv. **Establishing an occupational safety framework to increase awareness, detection and monitoring of cancer risk in the workplace.**

2. Evaluate existing sources of information, identify major knowledge gaps and introduce new approaches needed to assess and prevent occupational cancer risks. A register of known carcinogenic materials employed by the local industry will be introduced and compiled.

1.8.2 Environmental factors

Human health and well being are intrinsically linked to environmental quality. Good quality natural environments can offer numerous benefits to physical, mental and social well-being. However, environmental degradation — such as that caused by air and water pollution, noise, radiation, chemicals or biological agents — can have detrimental effects on health. Despite the considerable progress registered, substantial environmental health challenges remain. In addition to established problems — such as air, food and water pollution — knowledge about new and established health hazards continue to emerge (European Environment Agency, 2016).

Air pollution and in particular outdoors air pollution, is a major environmental health problem in Europe. Other environmental health exposures derive from consumer products that people are exposed to involuntarily in their daily life, such as paints or building materials in households, pesticides applied in gardens or playgrounds, chemicals used for cleaning at home, workplaces and in schools, and toys.

Air pollution is both an environmental and a social problem, as it leads to a multitude of adverse effects on human health, ecosystems, the built environment and the climate. Three major groups of air pollutants are of primary health importance in relation to outdoor air quality: particulate matter (PM)², ozone and heavy metals. Outdoor air pollution is a mixture of multiple pollutants originating from a myriad of natural and man-made sources such as transport, power generation, industrial activity, biomass burning, and domestic heating and cooking. The body of evidence for an association between PM and lung cancer is constantly becoming stronger (Raaschou-Nielsen, et al., 2013). Other substances or mixtures contributing to outdoor air pollution and that have been classified as carcinogenic by the International Agency for Research on Cancer (IARC), include diesel engine exhaust, benzene, polycyclic aromatic hydrocarbons, formaldehyde, toxic metals and many by-products of incomplete combustion (e.g. dioxins). Second-hand smoke (passive smoking), which contains the majority of the constituents of tobacco smoke, including 69 known carcinogens, is also a contributor to both indoor and outdoor air pollution (Leon, et al., 2015).

Other environmental contaminants can be found in food and water and these include a wide range of compounds such as pesticides, industrial and household chemicals, metals and pharmaceutical products. Of special concern are chemical contaminants with persistent and bio-accumulative properties, as well as potentially endocrine disrupting properties as these can modify the hormonal and homeostatic systems and have consequently been related with an array of diseases and disorders. These chemicals are often found in plastics, textiles, cosmetics, dyes, children's toys and baby-care products, lubricants, pesticides, electronic goods and food packaging. When these are discarded as waste, several of these chemicals can easily migrate to the environment and can be found in wildlife, outdoor air, indoor dust, wastewater and sludge.

There is extensive proof of the association between high doses of ionizing radiation and cancer in humans. Natural terrestrial and cosmic background radiation are the most important sources of ionizing radiation for humans. Nevertheless, man-made sources tend to give much greater public concern such as nuclear power production and nuclear accidents (e.g. Chernobyl, Fukushima). Radiation for screening, diagnostic and therapeutic purposes is also a matter of public concern. It is generally believed that the benefit from these interventions significantly surpasses the potential cancer risk incurred by radiation exposure. Nonetheless, needless exposure to ionizing radiation should be avoided, even though the collective exposure from diagnostic tests is small in comparison to the exposure to natural radiation (Boice, 2006), (Parkin, Boyd and Walker, 2011).

Another exposure that generates considerable public concern is non-ionizing radiation from sources such as mobile phones and power lines. To date, evidence does not strongly support the concern that current exposure levels have an associated risk of cancer. However, a number of studies have repeatedly shown (albeit with only limited evidence) that electro-magnetic fields are possibly carcinogenic for example in relation to increased risk for childhood cancers and especially childhood leukaemia (Kheifets, et al., 2011). On the other hand, the existing data linking exposure to electric or magnetic fields and cancers in adults is still considered as insufficient and inconclusive (IARC, 2002b).

2. Particulate matter (PM) is a pollutant comprising a complex mixture of solid and/or liquid particles of organic and inorganic substances suspended in the air.

Exposures to environmental and occupational carcinogens can be decreased or removed, and the cancers linked with these exposures can be prevented through policies that promote healthy working and living environments (Prüss-Üstün and Corvalán, 2007). There is also positive evidence that population-based policies and legislative tools to prevent environmental and occupational carcinogenic risks are feasible and highly effective in reducing cancer burden (Espina et al., 2013). Personal interventions can include ensuring adequate ventilation in private homes, the use of energy efficient household appliances to help to reduce indoor air pollution, careful disposal of household chemicals to minimise contamination of drinking water and soil and limiting the use of and proper maintenance of private cars.

A number of measures are being included in the National Cancer Plan to address the above issues. These include:

- 1. Design, support and conduct ongoing campaigns aimed at and adapted to various sectors of the population (policy makers, health care workers, local councils, general population, children and specific workers' groups) to increase awareness on many common environmental carcinogens and to inform and influence community and individual interventions to help reduce levels of contamination and minimise exposure.**
- 2. Improve public health safety by updating and upgrading the capacity of the National Reference Laboratory to perform analysis of an increased range of toxins and contaminants so as to improve and intensify:**
 - i. surveillance and monitoring services concerning chemical contaminants and toxins in food.**
 - ii. surveillance and monitoring services concerning chemical contaminants and pollutants in the environment that are known to increase the risk for different types of cancer.**

1.9 Other cancer determinants

1.9.1 Exogenous hormones

Hormones in oral contraceptives (OC) and post-menopausal hormone replacement therapy (HRT) have been linked to an increased risk of some cancer sites especially of the reproductive organs. Most of the risk has been shown to be mostly associated with current or recent users and is thought to decrease in the years following cessation. Several studies have shown an amplified risk for breast and cervical cancers in OC users and an increased risk for breast, ovary and uterus cancers in HRT users (risk pattern dependent on whether HRT is oestrogen-only or combined oestrogen-progestogen) (Lacey, 2006), (Parkin, Boyd and Walker, 2011). Oestrogen only HRT given to women without a uterus has been shown that while it lowers their risk for coronary heart events and osteoporotic fractures it does not alter their risk for breast cancer (NICE Guidelines, 2015). On the other hand, OC use has been shown to substantially reduce the risk of ovarian cancer and may reduce the risk of endometrial cancer (Friis, et al., 2015).

1.9.2 Immunological factors, hereditary risk of cancer and genetic modifiers of cancer risk

The knowledge on cancer aetiology, prevention and treatment is increasing in parallel with the advancing understanding on immunology. Both inherited and acquired immunodeficiency conditions have been linked to increases in cancer risk. Primary inherited immunodeficiency syndromes are rare disorders that increase the risk of recurrent and persistent infections, and may eventually lead to a higher risk of lympho-proliferative malignancies. On the other hand, acquired immunodeficiency (such as through immunosuppressive treatment and HIV infection) are known to increase risk for specific cancers such as Kaposi's sarcoma and non-Hodgkin's lymphoma and skin cancers (Morgan, 2006).

Cancer results from the breakdown in the genetic control of cell growth and behaviour. This fact underpins the importance of genetic factors in the risk for malignant neoplasms. Genetic anomalies and errors can be inherited and as a result whole families may be affected. Genetic studies, follow-up and databases of members of cancer prone families are discovering a relentlessly expanding list of familial cancer syndromes (Lindor et al., 2006). Discoveries have also led to the identification of specific genes that confer only mild-to-moderate increase in predisposition to cancer. Further research is also finding genes that contribute to the heritable component of the cause of cancer but do not have enough individual influence to account for families with a classic pattern of inheritance of cancer and therefore require other factors such environmental triggers or other unidentified genes to precipitate disease (Caporoso et al., 2006). These discoveries are offering new opportunities for more screening and accurate diagnosis (often before symptoms become manifest). Further intense work is required and this includes initiatives such participation in international research collaborations, multidisciplinary research, compilation and use of biobanks and large-scale population-based studies (Preston, 2007).

1.10 Conclusion

There is now an array of well-defined and well known lifestyle and environmental factors involved in the causation of cancer. These include tobacco smoking, alcohol consumption, dietary and nutritional factors, insufficient physical activity, occupational and other environmental risks and infectious agents. Several of these unhealthy lifestyle and environmental determinants are also causal or contributing factors in the causation and risk for other non-communicable diseases such as diabetes mellitus, cardiovascular disease and chronic obstructive pulmonary disease.

The European Code Against Cancer developed through the intense work of several groups of scientists delivers a practical framework for health promotion and cancer prevention, as well as alternative strategies to target the main causes of cancer. These strategies have been proven to be effective when appropriately implemented.

Cancer prevention is a complex undertaking that must involve stakeholders from many sectors of society and target the social and economic dimensions responsible for the cancer burden. Communication is key. In order to alter human behaviour so that healthier environments and lifestyles are adopted by more people, there is the need to deliver consistent messages using multiple channels of communication and design and apply effective strategies. Persuasive pragmatic and economic reasons can be used to inform advocacy for these policies because cancer has substantial direct and indirect impacts on national economies and places a tremendous social and economic burden on all communities and countries (Centres of Disease Control and Prevention, 2013).

1.11 Indicators

Most of the above measures require a considerable time lag before they will be fully implemented and the relevant information especially with regards to outcomes can be made available. Therefore, a number of structure and process indicators are being included to supplement and provide context to the outcome measures listed.

Type of Indicator	Indicator
Structure	<ul style="list-style-type: none"> Implementation of the Non-Communicable Disease Strategy, Food and Nutrition Policy and Action Plan, Whole of School approach to healthy lifestyles, Healthy Weight for Life Strategy, Communicable Disease Strategy and strategies to promote physical activity Preparation and publication of a new Tobacco Control Strategy Finalization and implementation of the National Alcohol Policy Existence of an occupational safety framework with national reporting mechanisms on safety related to the exposure to carcinogens in the workplace Allocation of money to fund specific actions, including explicit allocations for cancer epidemiology and public health research Existence of legislation regulating sun-bed use including banning its use by minors Revision of clinical protocols for primary and specialized care, to increase focus on prevention Existence of strategic aids to educators, businesses and industries to help these stakeholders prevent cancer in their settings
Process	<ul style="list-style-type: none"> Audit reports on enforcement of health protection legislation Number of interventions to treat tobacco or alcohol dependence Vaccination coverage for HPV and HBV Range of toxins analyzed by the National Reference Laboratory
Outcome	<ul style="list-style-type: none"> Cancer incidence and mortality rates, trends and projections* Prevalence of tobacco smoking among adults and young people (10-14 years old) disaggregated by gender and socio-economic groups* Consumption of alcohol*, disaggregated by gender and socio-economic groups Levels of and attitudes towards physical activity* Consumption per capita of fruits and vegetables* Body Mass Index distribution in the population* Prevalence of occupational exposure to carcinogens*

* EUROCHIP indicators: Available at: <http://www.tumori.net/eurochip/indicators.php?page=list>. (Accessed: October 2016).

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CHAPTER 3

IMPROVING SURVIVAL THROUGH CANCER SCREENING AND EARLY DIAGNOSIS

1.0 INTRODUCTION

Early detection of cancer greatly increases the chances for successful treatment. There are two major components for early detection in cancer: education to promote early diagnosis and screening (World Health Organisation, 2016).

Early diagnosis can be achieved through the recognition of possible warning signs of cancer followed by prompt and effective action. Awareness of and knowledge on possible warning signs of cancer, among physicians, nurses and other health care providers as well as among the general public, can have a vast impact on the disease. Examples of the initial visible signs of cancer include lumps, sores that fail to heal, abnormal bleeding, persistent indigestion, and chronic hoarseness. Early diagnosis is of particular relevance for cancers of the breast, cervix, mouth, larynx, colon and rectum, and skin.

Delays in diagnosis have been linked to poorer survival outcomes and in fact cancer survival is a key indicator of health-care system performance especially with regards to quality of care (Organization for Economic Co-Operation, 2015). The EURO CARE project on cancer survival in Europe showed that although substantial improvements in cancer survival has occurred in all European regions during the past two decades there are still major and persisting differences between the cancer survival rates registered for the same cancer site or type across different countries and regions included in this ongoing collaborative research project. Factors such as differences in stage at diagnosis, delay in diagnosis, accessibility to good care, screening practices and diagnostic intensity contribute to the variations documented in cancer survival between countries (Baili et al., 2015).

Screening involves testing for disease in people without symptoms, with the primary purpose of reducing mortality from the target disease. Cancer is always a potentially lethal disease. For this reason, the principal goal of screening for cancer and treating cancer patients is to save lives. Public health policies related to cancer screening are therefore invariably instigated, managed and assessed with the intention of reducing mortality. Consequently, mortality is the most important indicator of effectiveness (Coleman et al., 2008).

Cancer screening is appropriate when a cancer has a detectable preclinical phase during which it can be treated to prevent progression to overt, clinically detectable disease. Ideal screening programmes should be able to decrease the burden of disease in terms of mortality and morbidity, and/or improve the quality of life. Screen-detected cancer cases should have a better prognosis than those detected clinically, because the disease will have been treated in earlier phases of its natural history. However, screening programmes will always have some inherent undesirable effects. Screen-detected cases often include borderline abnormalities. Some of these abnormalities can fulfil the histological criteria for malignancy, but they will not progress even when left untreated, and would thus remain clinically indolent (IARC Working Group, 2005). Any screening programme will disclose such abnormalities and therefore one of the adverse effects of screening is over-diagnosis, i.e. detection of inactive or inconsequential pathology, and unnecessary treatment (over-treatment). Furthermore, there is no need of screening if a disease can be successfully treated after it has become clinically diagnosed and screening should not be applied to untreatable diseases (Coleman et al., 2008)

1.1 Screening for cancer

Population-based cancer screening programmes have proven effective in reducing the incidence or improving the prognosis of three common cancers: cervical, breast and colorectal. While screening procedures exist for some other sites, including prostate and lung cancers, more scientific evidence is required before these procedures meet basic effectiveness and cost-utility criteria (Martin-Moreno et al., 2015). Sub-sections 1.1.1 and 1.1.2 will exclusively address screening for cancers of the breast, large bowel (colon and rectum) and cervix uteri.

1.1.1 Screening activity in Malta

It is important to distinguish between organised population-based screening and opportunistic case-finding.

Organised population-based screening takes place when a test is offered systematically to all individuals in the defined target group within a framework of agreed policy, protocols, quality management, monitoring and evaluation. On the other hand, **opportunistic case-finding** occurs when a test is offered to an individual without symptoms of the disease. Frequently, these persons present to a health care practitioner for reasons unrelated to that disease.

Screening activity has been measured in all the three editions of the Health Interview Survey that have been performed in Malta since 2002. Tables 7a, 7b and 7c show time trends of the proportion of the population reporting to have undertaken screening procedures for breast, colorectal and cervical cancers at least once in their lifetime in the European Health Interview surveys for Malta for 2008 and 2014. This information does not distinguish between organised and opportunistic screening activity and referral for these interventions for suspicion of cancer..

Age groups (years)	European Health Interview Survey 2008	European Health Interview Survey 2014
15-29	5.6	3.5
30-39	14.7	12.6
40-49	48.5	49.5
50-59	53.7	90.4
60-69	48.7	76.7
70+	32.3	43.7
Total	32.5	43.1

Table 7a: Percentages of female respondents reporting having ever had a mammography by age group

Age groups (years)	European Health Interview Survey 2008	European Health Interview Survey 2014
15-29	39.0	41.1
30-39	85.9	93.8
40-49	88.8	95.2
50-59	81.5	91.3
60-69	63.6	81.2
70+	30.4	53.8
Total	65.4	74.2

Table 7b: Percentages of female respondents reporting having ever had a cytological smear of the cervix uteri by age group

Age groups (years)	European Health Interview Survey 2008	European Health Interview Survey 2014
15-29	2.4	4.4
30-39	3.1	8.0
40-49	4.6	12.7
50-59	5.7	16.0
60-69	8.5	32.4
70+	6.4	21.7
Total	4.7	14.6

Table 7c: Percentages of respondents reporting ever having had a faecal occult blood (FOB) test by age group

Source: European Health Interview Surveys – 2008 and 2014, Directorate for Health Information and Research, Ministry for Health, Malta

The proportion of women reporting to ever having a mammogram showed a marked increase in the 2014 survey results from the outcome of the 2008 survey in the 50 to 69 year age groups. There are smaller but more widespread increases in the women reporting that they had at least one cytological smear of the cervix over the same time period with women below the age of 50 years superseding the 90% level. Activity with faecal occult blood test shows an almost four-fold increase in the 60 to 69 years age group and three-fold increase in people 70 years and older. Analysis by educational level of the respondents of the 2014 survey did not yield any remarkable results possibly because the higher levels tend to be skewed towards the younger age groups while the lower levels are generally more prevalent in the older age cohorts. Therefore, no meaningful patterns could be extracted.

These findings can infer that the general awareness for the three different types of cancer screening activity analysed is increasing with time. Both the introduction of organised national screening programmes as well as the generally increasing health awareness and literacy levels in the population can be named as important factors leading towards these affirmative developments.

1.1.2 Organised screening programmes

An organised population-based screening program necessitates an integrated process where all activities along the screening pathway are planned, coordinated, monitored and evaluated through a quality improvement framework. Any national screening programme that is introduced and implemented should employ good governance with well-functioning evaluation and quality assurance structures in order to meet established standards, make use of evidence-based tests and provide a cost-effective service that is of the highest quality. All of these activities must be adequately resourced to ensure that benefits are maximised.

1.1.2.1 Improving the quality assurance and management of population cancer screening programmes

The process of screening involves testing for the possible presence of as yet undiagnosed disease in individuals who are not yet symptomatic. It therefore requires tests to be carried out on a large number of apparently healthy people to identify early evidence of an abnormality or disease. Individuals who test positive are subsequently investigated further with often more invasive diagnostic tests and those with confirmed disease are offered appropriate treatment and follow-up. In the vast majority of screen detected cancer cases this should lead to the expectations of a better health outcome than if the disease was left undiscovered and thence diagnosed at a later stage.

It is essential that the quality of screening programmes is upheld and continuously improved. For these reasons, ongoing evaluation and quality control should form an integral part of any screening programme. This will ensure that the programme is achieving what it set out to do and meeting its original objectives and is doing so by means of a methodology that is acceptable to those involved and which meets appropriate standards. The importance of having effective systems of quality assurance cannot be underestimated. Quality Assurance (QA) may be defined as"all those activities designed not only to reduce the probability of quality failure but also to improve performance continuously" (Gray and Austoker, 1998).

The general principles that facilities should focus on in terms of guaranteeing the quality of the screening programme include the:

- Capacity for screening;
- Quality of samples collected and examinations undertaken;
- Accuracy of analyses;
- Consistency in protocols;
- Competencies of health professionals engaged with the programme (Martin-Moreno et al., 2015).

The take-up of screening varies greatly between different geographical areas and different socioeconomic groups. While more affluent and better educated members of the population who are generally at lower risk are more likely to accept invitations for screening, those in the more deprived sectors and who are at higher risk do not. It is important that strategies are devised and implemented to improve any causes that may be leading to inequity of access.

A strong, versatile and appropriately resourced governance model is essential for maintaining and improving quality standards and performance objectives inter alia recall rates, interval cancer rates and acceptance/ participation rates of the invited persons in the population. Another important objective is to ensure sustainability. This vital consideration necessitates:

- Active and long-term government commitment to provide the required sustainable resources to establish and tailor the expansion of the programmes
- Investment in quality assurance. The capacity for this function should be regularly benchmarked with the levels recommended in the European quality assurance guidelines (between 10-20% of the recurrent programme expenditure) and regularly reported (Martin-Moreno et al., 2015).

Finally, an important pre-requisite is an effective working relationship between the national cancer screening setup and the national cancer registry. Information from the registry is essential for the determination of several of the performance outcomes of cancer screening programmes.

This National Cancer Plan is promoting the following measures to ensure good management and quality of the national cancer screening programmes:

1. **Continue to regularly update national policies for cancer screening. A major aim of these policies is to establish and monitor the governance structure and processes of the national cancer screening setup in Malta. These policies support and regulate the ongoing operations as well as the introduction, review, updating and implementation of continuous improvements of the screening programs.**
2. **Conduct in-depth assessments to ascertain the reasons for participation and non-participation in cancer screening programmes. Regular audit cycles for each screening programme will be planned and conducted.**
3. **Implement targeted actions designed to reduce socio-economic, cultural and regional inequalities in the access to and take-up of screening.**
4. **Consolidate and augment quality surveillance, evaluation and control systems and publish program performance and outcome indicators. Further develop and consolidate the interconnectivity between the national cancer screening setup and the national cancer registry.**
5. **Develop and support structured training, re-training, continuous professional development (CPD) and systematic assessment of all staff involved in the implementation of cancer screening programs.**
6. **Ensure that the national cancer screening setup in Malta develops and maintains the capability to interact, participate and contribute to international cancer screening networks and research collaborations. This capacity will also enable it to keep updated on emerging evidence and recommendations on new and emerging mass screening protocols and recommendation for screening programmes concerning other cancer sites such as prostate, stomach, ovary and lung.**

1.1.2.2 Approaching the target groups and frequency of the established national screening programs in line with best evidence and practice and updated EU guidelines

Organised, population-based cancer screening programmes were introduced in Malta with the start of the breast screening programme in late 2009. This was followed by the colorectal screening programme in 2012 and the cervical screening programme in 2015. The three national cancer screening programmes were all started by inviting age cohorts that were substantially smaller than those recommended by the EU Council Recommendation on Cancer Screening (2003) and their respective EU Guidelines (Segnan, Patnick and von Karsa, 2010), (Arbyn et al., 2008), (Perry et al., 2006). The main justification for 'starting small' to be followed by gradual expansion in each programme stemmed from the considerable difficulties of introducing new programmes in a small country where pilot start-ups involving only a selected subset of the population residing in a circumscribed region may not be acceptable or indeed feasible.

The age range to be covered and the screening interval are major organizational considerations in any screening programme. Table 8 shows the age cohorts and frequency of invitation for screening at the start of each cancer screening programme, in 2015, and the recommended age cohorts and screening intervals documented in the respective EU Guidelines.

Cancer Screening Programme (screening intervention)	At the time of the introduction of the programme: age cohorts and frequency of invitation	In 2015: age cohorts and frequency of invitation	Recommended age cohorts and frequency of invitation in the EU Guidelines ⁴
Breast screening (mammography)	2009: Women aged 50-60 every 3 years	Women aged 50-66 every 3 years	Women aged 50-69 every 2 years
Colorectal screening (FOBT)	2012: Women and men aged 60-64 every 2 years	Women and men aged 59-64 every 2 years	Women and men aged 50-74 every 2 years
Cervical screening (cytology)	2015: Women aged 25-35 every 3 years	Not applicable	Women aged from 25-30 up to 60-65 Years every 3-5 years
FOBT = Faecal Occult Blood Test			

Table 8: Age cohorts and frequency of invitation for screening at the start of each cancer screening programme, in 2015, and the recommended age cohorts and frequency documented in the respective EU Guidelines.

This National Cancer Plan is setting out strategies for the gradual expansion of each programme over the next five years with the ultimate aim of incrementally approaching the evidence-based practice and recommendations promoted in the respective EU Guidelines.

Furthermore, an in-depth evaluation will be conducted with a view of introducing plans to include people with determined higher risk for breast, colorectal and cervical cancer outside the regular age cohorts invited to attend the national cancer screening programs.

1.1.3 Risk-based approaches to cancer screening

Selective screening involves applying screening tests to proportions of the population that are identified to be at above-average risk for disease. Evaluation of existing methods of selective screening, based on reported risk factors only, are often not sufficiently valid to be merit incorporation into public health policy.

However, progressively over time, the acknowledgement and detection of inherited genetic mutations is becoming more proficient in the identification of persons with substantially increased risk for a number of cancers when compared to the rest of the population. Examples include the estimation of a three-fold increased risk of breast (i.e. to a 1 in 3 risk) in 0.7% of women in the United Kingdom based on a NICE algorithm that focuses on family history (Evans et al., 2014) and a six-fold increased risk of prostate cancer (i.e. to a 1 in 2 risk) in 1% of men compared to the rest of the population in a meta-analysis of genome-wide association studies that identified 76 common risk loci that can be traced through ancestry and family history (Al Olama, 2014). This advancing knowledge needs to be translated into programmes that can support individuals in prevention and/or active surveillance, as well as providing appropriate genetic counselling, given the potential implications for their family members. Detection tests for genetic mutations such as BRCA1 and BRCA2 which account to about 2% of all breast cancers (between 45 to 90% of women with these mutations will develop breast cancer during their lifetime and a smaller proportion will develop ovarian cancer) and

in hereditary non-polyposis colorectal cancer (Lynch Syndrome) that accounts for around 5% of all colon cancers are now well established. Recommendations to test women diagnosed with breast cancer and persons diagnosed with bowel cancer below the age of 50 years have been published by a number of reputable sources (The National Institute for Health and Care Excellence, 2013), (Loughrey, Quirke and Shephard, 2014). These tests can facilitate access to the most relevant treatment and enable family members to understand their own risk and take preventative action where appropriate. This may include more regular screening, use of chemo-preventive agents such as tamoxifen, or other prophylactic measures such as bilateral mastectomy.

This Plan is promoting the following measures to help develop the services required (including genetic diagnostics and counselling services) in order to increase the national capacity to identify, inform and appropriately manage persons presented with concerns related to potential high risk for cancer. These include:

- 1. Promote the evaluation of familial risk of cancer by using evidence-based screening tools designed to identify a family history that may be associated with an increased risk for potentially harmful mutations. People with positive screening results should receive genetic counselling and, if indicated after counselling, they are then referred for the appropriate genetic investigations.**
- 2. Increase the capacity for the conduction of more genetic cancer predisposition tests where indicated (such as the detection of BRCA1/2 mutation for breast and ovarian cancer and genetic mutations related to hereditary forms of cancer of the colon).**
- 3. Set up a steering group tasked with defining and developing a National Plan for Public Health Genomics.**

The implementation of these measures necessitates a concurrent and extensive re-structuring exercise of the genetics infrastructure and services offered by the public health service. Joint collaboration with facilities available in other sectors such as at the University of Malta need to be further developed in order to ascertain optimal use of all available resources.

1.2 Early diagnosis

This sub-section concentrates on other aspects to diagnosing cancer at an earlier stage apart from screening. It focuses mainly on patients that present with symptoms and signs that can be indicative of cancer and how the agility of referral and the diagnostic pathway can impact on the expectations for quality of life, prognosis and survival. The primary healthcare sector plays a crucial and leading role in determining the health system's performance at this initial stage of the cancer care pathway.

Early diagnosis can improve the quality of life of cancer patients by allowing a wider range of treatment options, the possibility of avoiding radical surgery (and possibly adjuvant chemotherapy and radiotherapy) and their chances of a full recovery can be considerably improved. For example, more than 90% of patients diagnosed at the earliest stages of bowel cancer survive at least five years compared with less than 7% of those diagnosed with the most advanced stage disease. The same pattern is true for lung cancer, breast cancer, and for many other common and rare cancers. Furthermore, it has been shown that some groups of patients are more likely to be diagnosed with later stage disease than others due to various reasons including inequality of access (National Awareness and Early Diagnosis Initiative, 2013). There are many possible factors which can affect the stage of disease at diagnosis and we need to tackle each element of potential delay.

People need information about how best to manage their health and when to seek professional advice. The 'fear' of cancer can be positively influenced by more openness and by placing greater emphasis on the benefits of early diagnosis. The management of patients in whom cancer may be suspected (or in due course excluded as a possible diagnosis) requires the availability of the applicable numbers of adequately trained health professionals who can identify indications for further action, including prompt access to blood tests, radiological imaging, ultrasound examinations and/or endoscopy. Clear procedures including processes for rapid access (fast-tracking systems) supported by local guidelines should be in place to ensure that patients who may have cancer have prompt access to the relevant specialists and multi-disciplinary teams. However, it is important to note that several persons with indicative signs and symptoms of cancer will not be found to have the disease at the end of the investigative process.

Evidence from the EURO CARE studies indicates that the differences in cancer survival between EU Member States, and between Europe and the United States, can be partly explained by differences in the stage at presentation (Sant, 2015). It is much harder to determine why these differences arise but better understanding of the reasons for delay in presentation or diagnosis should lead to improved access to cancer services. Socio-economic factors also play an influential part, as do the capacity and operations of the health systems. The latter is impacted by the available numbers and expertise of the doctors who first see the patient, the ease of access to key investigations such as endoscopy and the availability and capacity of the specialist cancer services. Clinical policies and guidelines play a key role in addressing these issues effectively within a health system.

There are several factors that can affect the stage of disease at diagnosis and each element of potential delay needs to be tackled. This National Cancer Plan is including a number of measures to address the following objectives:

1. Raising awareness of what to look out for and when to act and tackling negative attitudes to cancer and barriers to approaching the healthcare professionals especially the family doctor with concerns.
2. Supporting primary care professionals so they can be able to detect and better manage and refer patients with symptoms that may be indicative of underlying malignant disease.
3. Ensuring optimum and prompt access to diagnostic tests and referral pathways that can expedite the diagnosis and thereafter the treatment of cancer.

The Plan is advancing the following measures in order to:

- 1. Raise awareness on cancer symptoms and address negative attitudes and beliefs regarding cancer management that could lead to delays in seeking professional advice which in turn contributes to delays in diagnosis and treatment:**
 - i. Design public information strategies to help develop more health conscious behaviours in individuals and to strengthen personal skills for self-examination particularly in younger age groups (e.g. breast awareness, testicular examination and skin inspection) and early identification of symptoms that can be suspicious for cancer such as newly discovered and growing lumps, sores that fail to heal, abnormal bleeding, persistent indigestion, and chronic hoarseness.**
 - ii. Increase the spread, scope and uptake of the 'Lifestyle clinics' in primary healthcare.**
 - iii. Conduct research on health behaviour, particularly the barriers for seeking care in the face of suspicious symptoms and signs of cancer as well as the preferred method of care delivery.**
 - iv. Putting in place mechanisms for the evaluation of educational interventions.**

- v. Train family practitioners and other health care professionals (HCPs) to recognise 'red flags' and how to refer adequately to secondary care:
2. Design and conduct CPD activities to increase the awareness and capabilities of HCPs to recognise early symptoms and signs that can be suspicious of cancer and to take necessary actions and refer the patients for pertinent investigations and expertise.
 3. Develop and disseminate decision-making support tools for family practitioners to assist them in the assessment and follow-up of patients with various forms of cancer (including the detection of secondary cancers and recurrences). These instruments can be incorporated into the design of fast-track referral tools.
 4. Further develop secure and user-friendly channels of communication between professionals working in primary healthcare and other health services.
 5. Improve referral pathways and diagnostic capacity:
 - i. Study referral pathways with the aim of determining feasible national timeline standards from 'Urgent suspected cancer referral' to 'First treatment'.
 - ii. Further develop and invest in the necessary ICT infrastructure and tools to facilitate referrals from screening/primary care to secondary care with the aim to address bottlenecks, accelerate referrals and raise quality standards. These tools will also assist in the required improvements in the performance and outcomes measurement of the systems for screening, early diagnosis and fast-tracking of persons with symptoms and signs that are suspicious of cancer.
 - iii. Ensure the acquisition of the necessary investment to increase diagnostic capacity (expertise and equipment) so that the cancer control services can cope with the current and the forecasted steady increases in demand for these services.

1.3 Conclusion

For several cancers early diagnosis is the key to a good or better prognosis. However, lack of public (and sometimes health care professionals') knowledge and awareness of the potential signs and symptoms, and fear or lack of responsiveness by the healthcare professional and services to these indications, can lead to possible deleterious delays in diagnosis and thereafter the onset of the appropriate treatments.

Earlier diagnosis is associated with improved survival and postponement of death which in most cases is more than what can be ascribed to lead-time bias (i.e. length of time by which diagnosis has been brought forward) or alternatively over-diagnosis. Screening programmes have proved to be effective in reducing death rates for cancers of the cervix uteri, breast and large bowel (colon and rectum). It has also been shown that start of earlier treatment is important in reducing mortality rates for several other cancers. Longer survival reflects greater and more efficient investment in cancer control across the whole cancer care pathway, regardless of whether it is due to earlier diagnosis or to better treatment.

1.4 Indicators

Quality control is dependent on the ability to measure results. To help health system managers to identify the strengths and weaknesses of a screening programme and initiatives to increase the likelihood of earlier diagnoses, indicators need to be able to represent the three important dimensions of structures, processes and outcomes. Data gathering

required by these indicators involves several stakeholders and data repositories which include population registers, client databases and population-based cancer registries. Established and functioning processes for data linkages between all these databases is essential. Furthermore, regular quality audits for samples and diagnosis, service user satisfaction surveys and ad hoc modelling and simulation methods to estimate QALYs (quality-adjusted life years) and cost-effectiveness are necessary exercises that require resources and specific expertise to implement (Martin-Moreno et al., 2015).

Type of Indicator	Indicator
Structure	<ul style="list-style-type: none"> Number of available, qualified professional staff to carry out screening services Equipment available to carry out screening tests and analysis Administrative infrastructure to handle recruitment and follow-up Specific budget dedicated to cancer screening Spread, scope and uptake of the 'Lifestyle clinics' Numbers and expertise of the doctors and other HCPs in primary healthcare Composition and expertise professionals working in the national cancer registry
Process	<ul style="list-style-type: none"> % of women that have undergone mammography*, disaggregated by population groups % of women that have undergone cervical cytology examination*, disaggregated by population groups % of persons that have undergone a CRC screening test*, disaggregated by population groups Organised screening coverage (coverage by invitation) * Screening recall rate* Screening specificity* (the ability to designate an individual who does not have a disease as negative) Screening sensitivity (the test's ability to designate an individual with disease as positive) Screening detection rate* Screening localized cancers* Screening benign/malignant biopsy ratio* Screening interval cancers* % expenditure for quality assurance Service users' satisfaction surveys Waiting times for screening and follow-up Interval between screening test and issue of test result Number of cancer sites adopting a fast-track system Communications channels operating between primary healthcare and other health services and corresponding activity**

Continues on page 53

Continued from page 52

Type of Indicator	Indicator
Outcome	<ul style="list-style-type: none"> • Disease incidence[†] • Disease mortality (in screened and unscreened population) • Stage at diagnosis of screen-detected cancers • Population coverage (%) • Cost-effectiveness • Quality-adjusted life years (QALYs) gained[‡] • Interval cancer rate • Detection rate • Proportion of screen-detected invasive cancers ≤ 10 mm • Proportion of screen-detected cancers that are invasive • Proportion of screen-detected cancers with lymph node metastases • Awareness in the general population that cancer risk increases with age and ability to recognise/ associate symptoms and signs with cancer^{**} • Number of patients referred through the available fast-track systems and proportion of patients with confirmed diagnosis of cancer • Attendance at the 'Lifestyles Clinics' • Timelines between 'Urgent suspected cancer referral' to 'First treatment'^{***} • The number of times patients saw a health care professional before a cancer diagnosis is made^{**}

* EUROCHIP indicators: Available at: <http://www.tumori.net/eurochip/indicators.php?page=list>. (Accessed: November 2016).

** Cancer Research UK (2014) international cancer benchmarking partnership showcasing our findings and impacts.

Available at: https://www.cancerresearchuk.org/sites/default/files/icbp_pb_1012214_booklet_final.pdf. (Accessed: November 2016).

[†] Incidence should actually rise when a programme is first implemented, as this will indicate that more cancers are being detected. Once the programme has been fully rolled out, incidence should stabilize somewhat for breast cancer (also depending on the effectiveness of primary prevention measures), or decrease in the case of cervical or colorectal cancers, whose long latent period should allow detection of pre-cancerous lesions before a tumour actually forms (Martin-Moreno et al., 2015).

[‡] Although the calculation of QALYs is impaired by certain methodological challenges, it remains important to estimate QALYs for all patients who receive a positive diagnosis in order to ensure that life years are not presumptively gained at the expense of quality-of-life. This can happen if over-diagnosis or over-treatment lead to painful and distressful interventions among many patients who see no commensurate improvements in their life (Martin-Moreno et al., 2015).

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CHAPTER 4

IMPROVING SURVIVAL AND QUALITY OF LIFE THROUGH INTEGRATED CANCER CARE

1.0 INTRODUCTION

All patients should have access to a uniformly high quality of care in the community or hospital wherever they may live to ensure the maximum possible cure rates and best quality of life. Care should be provided as close to the patient's home as is compatible with high quality, safe and effective treatment (Calman-Hine report, 1995).

Cancer care is increasingly complex. Several medical specialities and professional disciplines are involved in the diagnostic and therapeutic process. Furthermore, the progress being made in research is resulting in continuous innovations with different levels of evidence and impact on outcomes.

A remarkable wide range of professional expertise and contributions from organizations at all levels of the health system and beyond need to be involved and therefore, planned activity is required across the full spectrum of interventions to integrate services with the ultimate aim of improving population and individual outcomes. The struggles of discontinuity and lack of co-ordination of care, faced by cancer patients, can be linked to the staggering amount of healthcare professionals they encounter during their cancer journey.

All these factors have made the organisation of the delivery of cancer care a challenge for health-care services, especially in terms of coordinating health professionals, multi-disciplinary teams and levels of care involved in the patient pathway over the course of the diagnostic and therapeutic process (Coleman et al., 2008). The lack of such an integrated care system for people with cancer was identified as a major pitfall of today's health system, prompting European initiatives and partnerships to improve cancer care services across the board (European Commission, 2009).

Integrated care pathways (ICPs) are structured, multi-disciplinary care plans for a specific clinical condition, which map out and describe the tasks to be performed, their timing, sequence, and the professionals and departments involved. ICPs serve as strategies of patient care improvement and may also encourage the adherence to clinical guidelines in routine practice (Fasola et al., 2012). They provide a seamless roadmap of care that spans across primary, secondary and tertiary care flows and across several organisational boundaries.

Cancer outcomes can be influenced by interventions of all types – from primary prevention to end-of-life care. Early diagnosis and improvements in therapy have resulted in substantial and widespread gains in cancer survival and in turn this has led towards increasing emphasis on and motivation for services related to rehabilitation and survivorship and also increasing the importance ascribed to the measurement of performance in relation to the quality of life of cancer patients during and after the completion of acute cancer care.

The resources required to address and cope with these challenges are always limited. Policy-makers are frequently tasked with the identification of areas for improvements, establishing priorities and selecting actions that could offer a clear population benefit and improve the experience of care for patients (Martin-Moreno et al., 2015).

The guiding principle with regards to resource utilisation is that available resources are employed effectively and efficiently and that the structures and processes utilised for the delivery of cancer services should be those most likely to produce good and desired outcomes.

The key outcome measure in cancer control services is survival. However, this is neither the only valuable outcome nor, for several patients, the most important. Other important outcomes include the quality of life resulting from combinations of well-being, psychosocial factors and the impact of different forms of morbidity and the patient's experience of cancer and the care they receive. These outcomes can bear special importance to the cancer patients because they often require prolonged healthcare and are consequently rated equally or even higher than survival by the patients, their families and friends. Morbidity results both from the cancer itself and from its treatment. However, it can often be prevented or curtailed by good and effective clinical management.

Therefore, another fundamental guiding principle should be the participation of patients in the care process. The model of care that is applied should be based on communication with patients and shared decision-making whenever possible and appropriate. Cancer services need to be patient-centred and should take account of patients', families' and carers' views and preferences (particularly those affecting their quality of life) as well as those of professionals involved in cancer care (Calman-Hine, 1995). It is acknowledged that individuals' perceptions of their needs may differ from those of the professionals and therefore effective interaction and communication channels between professionals and patients are especially valuable. Likewise, patients should have access to a second opinion and the opportunity to choose from different treatments and care providers (European Commission, 2009).

A comprehensive cancer plan must address the full spectrum of clinical diagnostic and therapeutic services operating across and interconnecting the primary, secondary and tertiary healthcare systems domains. Following screening and early diagnosis, health systems need to tackle access to services for symptomatic diagnosis, staging and primary treatment, rehabilitation, survivorship, palliative and psychosocial care. For several patients, the care pathway will also involve the management of progressive or recurrent disease and end-of-life care complemented by the appropriate palliative and psychosocial support. All these major care sectors and their principal connectivities are being diagrammatically represented in Figure 8 below. Primary care services should be able to intervene across all the different phases, while psychosocial and palliative care services should be accessible from the moment of the initial definitive diagnosis.

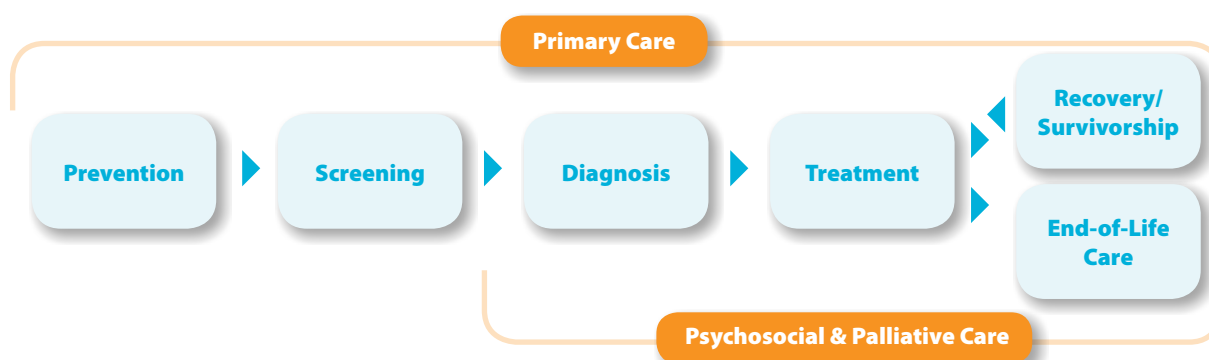


Figure 8 depicts these different phases along the cancer care continuum

Source: CCO - Cancer Care Ontario (2015) Ontario cancer plan IV 2015 - 2019.

Available at: <https://cancercare.on.ca/common/pages/UserFile.aspx?fileId=333871>. (Accessed: November 2016).

This chapter will elaborate on all the above care services and it will be divided into the following two major sections that include:

- A. Improving Diagnosis and Treatment
- B. Improving the Quality of Life of Cancer Patients

At the end of each major section a number of indicators will be included. These indicators will be used to assess the general progress in the cancer care services in Malta over the next five years and the implementation of this National Cancer Plan in particular. These indicators are useful for all the stakeholders involved: policy makers, hospital managers, all clinicians, patients and the general public. The Plan advocates the need that all clinicians involved in cancer care and control should have access to their own performance data.

A. IMPROVING DIAGNOSIS AND TREATMENT

The ageing of the population and the unrelenting expansion and sophistication of the knowledge and treatment options for the management of cancer will continue to drive growth in the demand for cancer care services. Improvements in early diagnosis will also mean more patients will require access to treatments that offer them the best possible outcomes. Furthermore, improving the rates of diagnosis must also be intimately linked to efforts to reduce the current variations in treatment and end-results. Most cancer patients will need a combination of diagnostic services including histo/ cyto-pathology and imaging interventions as well as combinations of surgery, radiotherapy and chemotherapy. Tackling a 'bottleneck' in one area should not result in the creation of a 'traffic jam' in the subsequent steps along the cancer care pathway.

Attributable to the complex nature of cancer care, the cancer patient can get lost in many places within the system, thereby causing unnecessary morbidity, delay in care and undue distress. Waiting for a diagnosis or the commencement of treatment is known to perpetrate anxiety to the patient and family and may also be painful and debilitating. Patients with cancer have physical, psychological, social, informational, emotional and spiritual needs. Unfortunately, due to the complexity of cancer care and the multiple health care professionals that the patients and their family come in contact with, the patient may experience a sense of disjointed care that lacks continuity or structure. This may further increase uncertainty and distress especially if gaps are present in the care provided.

Therefore, the planning for improvements in, and provision of each of these diagnostic and treatment modalities cannot be considered in isolation and an integrated approach needs to be consistently adopted throughout. This section is further sub-divided into two broad divisions. The first sub-division (A1) concentrates more on the diagnostic end of the pathway while the second part (A2) focuses more on the therapeutic components. It is worth noting however, that the distinction between these two areas is not clear-cut and a number of interventions can bridge activity and substantially influence output and outcomes across both areas.

A1. Improving accessibility to and availability of high-quality services for the diagnosis of cancer

This sub-section will be further sub-divided into the following:

- A1.1: Strengthening coordination between and within specialised/ secondary and primary health care
- A1.2: Addressing waiting times and rapid fast-track systems up to the start of treatment
- A1.3: Maintaining and improving the quality of diagnostics performed in the Pathology Laboratories
- A1.4: Maintaining and improving the quality of diagnostics performed in the Imaging Department and evaluating the possibilities of introducing and increasing the scope of interventional radiology in cancer care

A1.1: Strengthening coordination between and within specialised/ secondary and primary health care

There is an increasing appeal for greater involvement of the primary healthcare especially for the engagement of the family practitioner across the whole cancer care journey from prevention, through diagnosis and treatment and into follow-up and after-care. This is driven by a number of factors including the increasing request to provide services in the community and closer to the patient's residence and also the growing numbers of cancer patients and survivors.

In a number of health systems, the critical role for the coordination of cancer care has been assigned to healthcare professionals that assume the function of pathway navigators. Frequently these roles are specifically taken up by nursing professionals. The role of an oncology nurse navigator has been defined as follows:

"An oncology nurse navigator (ONN) is a professional registered nurse with oncology-specific clinical knowledge who offers individualized assistance to patients, families, and caregivers to help overcome healthcare system barriers. Using the nursing process, an ONN provides education and resources to facilitate informed decision making and timely access to quality health and psychosocial care throughout all phases of the cancer continuum"

ONS, 2013, p. 6

The navigator role has been shown to result in improvements in effective patient outcomes, person-centred care, and integrated services. The navigator's role is also considered as influential in addressing equity which is a recognised core value of quality care (Institute of Medicine, 2001). A central function of navigation is to recognize and eliminate barriers to care or bridge service delivery gaps, thus addressing health inequalities and supporting those patients that are more likely to be at risk for delays (Institute of Medicine, 2009).

This National Cancer Plan is advocating and supporting the following measures with the aim of developing and ensuring a dynamic co-ordination and flow of information between primary care and the various specialised care services at secondary and tertiary level.

- 1. Establishing and communicating well-founded criteria and guidelines for the elucidation and determination of clinical suspicion of cancer for the main tumours, the best indicated reference diagnostic tests and the priority/preferential processes for referral of patients to specialist clinics. The practice of establishing new fast-tracking systems including the development of e-forms to expedite and increase the necessary detail in the clinical information communicated between the family practitioners and the specialists in the referral process will be continued and consolidated with the incremental inclusion of more tumour sites and tumour groups.**
- 2. Establishing and maintaining a dynamic dialogue with the aim of reaching agreements between primary health care physicians and hospital specialists about their respective roles in the diagnostic pathway and points of access to the processes required to confirm, refine or refute tentative diagnoses.**
- 3. Implementing further measures to increase the feasibility and usability of sharing medical data between health care professionals at all levels of care (through various ICT media and also through the organisation of opportunities to meet and discuss cases and emerging issues).**
- 4. Adopting and applying a learning-cycle approach in order to maintain the effectiveness of the above-mentioned implemented mechanisms.**

All the above measures necessitate the:

- i. strengthening of the complement of the required staff working in primary healthcare especially specialists in family medicine and specialist/practice nurses in order to increase availability and allow family practitioners to attend training as per training schedules.
- ii. selection of a Principal General Practitioner and a number of Senior General Practitioners to assume the roles of focal points on cancer care pathways in the primary healthcare domain in general and in each healthcare hub respectively.

5. Develop and implement the role of nurse navigator/ case manager. These case managers will be responsible for the coordination of patients' care management particularly during the diagnosis and active treatment phases. Although different approaches to improve coordination of the process of care could be envisaged, the role of nurse navigator, as a reference for both patients and professionals, is the most frequently implemented model described in the international literature.

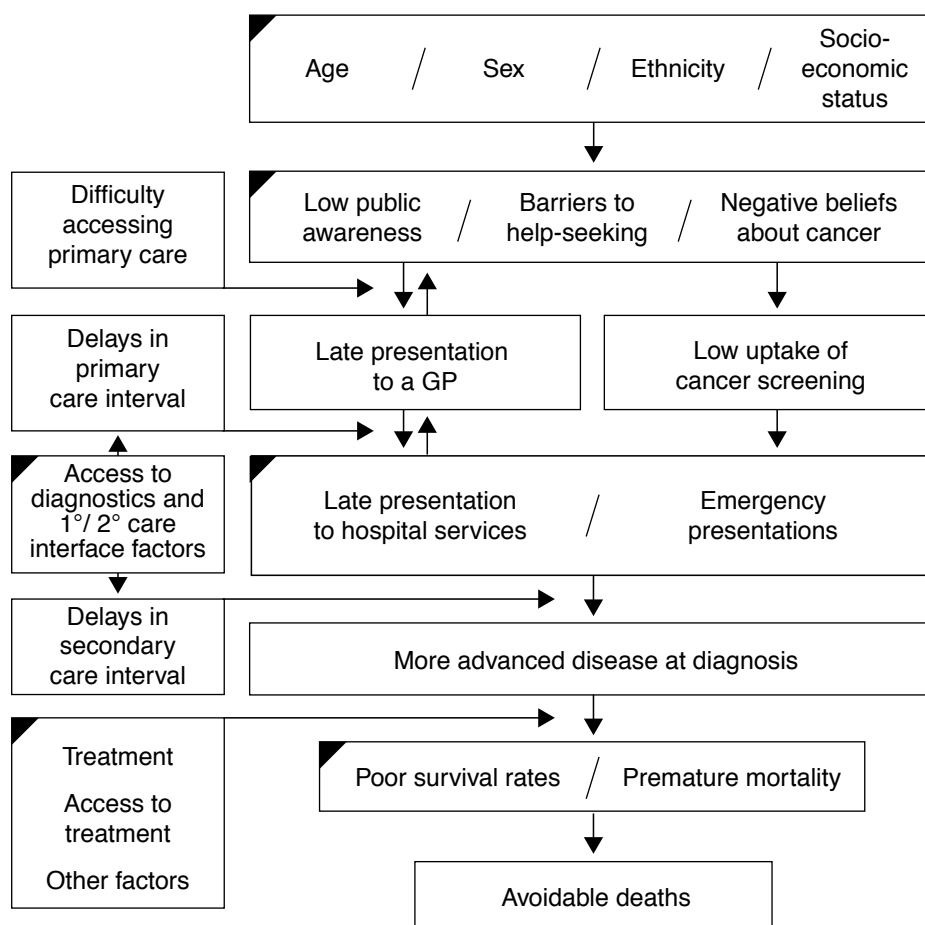
A1.2: Addressing waiting times and rapid fast-track systems up to the start of treatment

Every year primary healthcare physicians and professionals encounter several patients within their practice with symptoms and signs suspicious of cancer. Family practitioners are required to appraise these symptoms and decide whether to refer for an investigative test or intervention which may result in a definitive diagnosis. In almost all types of cancer, definitive diagnosis is only possible through a biopsy or tissue sample examined by a cellular pathologist. This is usually undertaken either concurrently with or subsequent to a range of blood tests and imaging or endoscopic interventions.

Diagnosing cancer at an advanced stage is a cause for substantial public concern. Achieving earlier diagnosis of cancer has therefore become a widely adopted priority for healthcare systems. Expediting a diagnosis of cancer is generally held as leading to a better prognosis, because cancer detected at an earlier stage has better treatment options leading to improved survival. This assumption is supported by evidence that tumours can progress during the time taken to reach a diagnosis and the start of treatment; observational studies indicate an evident association between time to diagnosis and mortality (Møller et al., 2015), (Richards, 2009), (Tørring et al., 2013).

An exercise aimed at assembling the diverse evidence linking late diagnosis with poor survival and avoidable deaths published in 2009 led to the postulation of a 'NAEDI³ hypothesis' (Richards, 2009). An updated version of this pathway was published in 2015 and is reproduced in Figure 9 below. The updated version seeks to portray the multi-factorial and often non-linear nature of the pathways leading to diagnosis from the first onset of symptoms and the individual's response, to decisions and actions to seek help which leads to the first and subsequent interactions with the healthcare professionals, to onward referral, diagnosis and beyond (Hiom, 2015). Opportunities for 'delay' can occur at any or all of the points along these pathways (Walter et al., 2012) and inequalities and variations in the time intervals registered by different groups of patients justify the scope for meticulous monitoring and research to identify the underlying factors that can influence them positively or negatively (Whitaker, Scott and Wardle, 2015).

3. NAEDI = National Awareness and Early Diagnosis Initiative. This is a key commitment of the Cancer Reform Strategy of 2007 by the Department of Health in England. This initiative was launched in November 2008 and is co-led by the Department of Health and Cancer Research UK, with involvement of a wide range of other stakeholders, including the research community.



■ New or changed since original hypothesis

Figure 9. Updated NAEDI hypothesis. Factors influencing cancer survival and premature mortality
Source: Reproduced with permission from the authors: Figure 1 (page S2) in Hiom, S.C. (2015) 'Diagnosing cancer earlier: Reviewing the evidence for improving cancer survival. The National Awareness and Early Diagnosis Initiative in England: assessing the evidence 5 years on', *British Journal of Cancer*, 112, pp. S1-S5.

Timeliness in healthcare is the measurement of a patient's capacity to access a service, once a need has been recognized. It refers to the efficiency of care that is provided, while avoiding or mitigating anticipated delays. Timeliness of care has also been identified as one of the fundamental values of quality care (Institute of Medicine, 2009). Sophisticated healthcare, coupled with new technologies, complex and unstable economic and financial environments and increased demand have led to recurring increases in waiting times and delays. The use of information systems can assist in the measurement of demand and capacity so as to identify if and where demand and capacity are not in equilibrium. Other factors associated with patient and system delays in care are socioeconomic, ethnicity, symptomatology experience, attitudes of patients, diagnostic factors, communication barriers between patient and physician, disease management and histo--pathological characteristics of disease (Freitas and Weller, 2015). The development of and adherence to targets and set time-frames for the transition of patients from one stage to the next in the pathway of care are useful practices to improve the effectiveness of treatment and the quality of the services provided to cancer patients.

The Plan recognises the important requirement of setting and maintaining acceptable timelines in various parts of the patients' cancer care pathway. For this reason, it is listing the following measures to consolidate and continue the development of actions to continuously improve performance through:

1. The continuation of the research and ongoing surveillance with the aim of establishing explicit and reasonable nationally applicable waiting times for diagnostics and the start of treatments for cancer patients. This work will continue to be led by the Directorate for Cancer Care Pathways within the Department of Healthcare Services.
2. Investing in, developing and implementing sustainable and versatile computerized information systems that will electronically track individual cancer patients throughout their whole cancer care pathway (from screening or first referral to diagnosis, treatment, rehabilitation and palliative care and beyond)
3. Ensuring sustainable technical capacity (equipment and software availability and support accompanied with appropriately trained and supported human resources) for recording and monitoring key performance and quality indicators of the diagnostic and treatment processes, for analysing the results and feeding them into appropriate quality management processes.

A1.3: Maintaining and improving the quality of diagnostics performed by the Pathology Laboratories

Cellular pathology describes the group of pathology specialties that study changes in cells and tissues to make a diagnosis. Biopsies of tissue samples are common during the diagnostic process and most cancers are diagnosed after a pathologist microscopically examines tissue or cell samples of suspected malignant lesions. The pathological examination of a cancerous tissue or cell sample determines the precise type of the cancer. These include the characteristics of the cancer cells, indications on the stage or spread of the cancer in the body based on tumour size and location and may also provide information on other tumour characteristics such as the presence or absence of hormone receptors or other tumour markers. A complete and accurate pathology report is crucial to getting a precise diagnosis and for the decision-making concerning options for the treatment plan.

Diagnostic accuracy is progressively improving with the use of newer technologies that focus more on the molecular aspect of diagnosis and this is allowing cancers to be classified further through the identification of specific genes, proteins, and genetic mutations or alterations that drive tumour growth. Molecular technologies are not only providing additional insights into the heterogeneity of different types of cancer but have also opened new avenues for treatment through the identification of signalling molecules important in the proliferation and survival of the neoplastic cells. The treatment of cancer thus shifts from the conventional approach of 'one size fits all' to one of personalized treatment tailored to the specific characteristics of the tumour. The role of the pathologist as a diagnostic oncologist is therefore increasingly involving the complete spectrum or continuum of cancer care and extends from prevention and screening through diagnosis to prognosis and prediction of the therapeutic response and monitoring of the disease (Leong and Zhuang, 2011).

The size and composition of the healthcare workforce in general and the medical consultant workforce in particular at any time is largely the result of plans made 10 to 20 years before due to the time it takes to train entry-level doctors and for some of those doctors to reach consultant levels. Factors impacting on the complement of medical consultants needed for a particular service such as cellular pathology are compounded by new technologies, changing demographic needs and innovations in care models. According to an updated assessment and guidelines

issued by the Royal College of Pathologists in 2015, cellular pathologists spend up to 75% of their work-time on direct clinical care (microscopy and macroscopy) and the rest on supporting professional activities such as instruction and supervision of trainees (this is a consideration of increased importance in a teaching hospital), continued professional development and additional hospital responsibilities. These guidelines need to be extrapolated to the context of the public healthcare systems in Malta. Parallel growth in all the other professional groups operating in the pathology department especially the medical laboratory scientists need to be ensured and sustained in order to ensure the continued advancement of this essential healthcare service particularly for cancer care services.

The Plan foresees the need to continuously upgrade and update the pathology services especially where these impact cancer care services inter alia in the diagnosis and the monitoring of therapeutic response and disease regression or progression. The following measures will be implemented with the aim of achieving this objective:

- 1. Conduct regular 'gap' assessments and ongoing 'horizon scanning' for technological and scientific advances to identify the equipment and expertise required to achieve and continuously upgrade the capabilities of all the different specialised laboratories within the Pathology Department at MDH involved in the diagnosis and monitoring of cancer. These involve almost all sub-specialities in Pathology but particularly include cellular pathology (histology, cytology, immuno-histochemistry), molecular pathology, haematology, genetics, immunology, virology and biochemistry. Continued investment for the procurement of additional new equipment, updating of existing laboratory technology and the necessary physical infrastructure identified through these exercises is essential.**
- 2. High-quality pathology reporting is essential for the confirmation of a cancer diagnosis and for clinicians and multi-disciplinary teams to decide on the most appropriate course of treatment. Synoptic reporting is a clinical documentation method that provides for concise, standardised surgical pathology reporting which includes all the data necessary for accurate staging, treatment and prognosis. The process for the development and implementation of synoptic pathology reporting will be vigorously pursued during the time frame of this Plan.**
- 3. Double reading especially in the diagnostic process for rare tumours performed in conjunction with expert pathologists working in appropriate centre of expertise is an important practice to ensure and further cultivate high quality diagnostic services. Support for the establishment and maintenance of contacts and communications with relevant experts will be strengthened particularly with the upgrading of tools that will facilitate connectivity such as with the exploration for the introduction of digital pathology systems.**
- 4. Investing in, developing and implementing a sustainable setup for molecular diagnostics that will be able to respond to and expand with the forecasted and accelerated growth in this increasingly important branch in the pathological diagnosis and monitoring of cancer.**
- 5. Support and ensure the implementation of the appropriate accreditation processes of the whole pathology department within MDH and especially of the specialised laboratories involved in the diagnosis and monitoring of cancer.**

The planning for and implementation of the above measures necessitate that adequate capacity is achieved and maintained with regards to the volume, composition as well as expertise of the healthcare workforce operating in the pathology department. This requires special attention inter alia to the recruitment, correct staffing and division of tasks, the strengthening of specialist training and supporting programmes for continued professional education.

A1.4: Maintaining and improving the quality of diagnostics performed in the Imaging Department and evaluating the possibilities of introducing and increasing the scope of interventional radiology in cancer care

Radiology's role is central to cancer management, with a wide choice of tools and techniques available for the detection, staging and treatment of the disease (European Society of Radiology, 2012). Specialists in medical imaging – including all specialists in the fields of diagnostic and interventional radiology and nuclear medicine – are essential members of the multi-disciplinary team managing the diagnosis and treatment of cancer patients. The technological advances made in imaging equipment and the development of specific techniques for every stage of cancer care imply that the contribution of medical imaging, as well as the expertise of those who practise it, is indispensable.

Imaging techniques have significantly improved in recent decades and as technologies are constantly being refined, imaging modalities will become even more accurate and reliable in the future. Imaging plays a major role in the detection of cancer as it can provide a comprehensive insight into the exact location and extent of the disease. It can also provide detailed information about structural or cancer-related changes. Emerging methods of molecular imaging, combining traditional imaging technology with nuclear medicine techniques, can also be used to obtain more detailed information about abnormalities, including the distinct metabolism of tumour cells.

Radiologists' skills and experience in interpreting medical images play a crucial role in the determination of the precise extent or the spread of cancer and this in turn greatly influences the treatment options that can be considered at the multi-disciplinary level. Imaging also plays a fundamental role in the monitoring of therapy by allowing clinicians to gauge the effectiveness of the treatment plan. Another role of imaging in cancer treatment is the use of imaging modalities to localise and define treatment target volumes and image-guided techniques to ensure more accurate radiotherapy delivery to the tumour tissue while minimising the doses to the surrounding organs or tissues. Additionally, nuclear medicine physicians employ imaging technology to follow the movements of radio-pharmaceuticals (radioactive substances) in the body and determine whether they are reaching their target accurately and in sufficient quantity. Also, different modalities of imaging equipment are now increasingly being installed in surgical operating theatres (ibid.).

More recently, a growing number of image-guided therapies have widened the range of cancer treatment options especially with the advent of interventional radiology which is a sub-specialty of radiology that has been developing since the early 1970s. These techniques are usually minimally invasive (as compared to conventional surgery) and can be used in an increasing number of cancer sites and situations. Examples include embolisation (obstruction of the blood vessels that feed a tumour mass), radio-frequency ablation (using electromagnetic/radio waves to destroy tumour tissue) and selective internal radiation therapy (SIRT) through the injection of tiny microspheres of radioactive material directly into the arteries that supply the tumour.

Imaging also plays an important function in the monitoring of patients after the completion of treatment as it can help clinicians to non-invasively detect the state of the disease or its recurrence before symptoms appear and as such it is also a cornerstone of follow-up cancer care.

A sustained effort to increase the complement of radiologists (including specialists in nuclear medicine) is required and this also entails an increased effort to attract, retain and complete the specialisation training programme of medical specialist trainees in radiology. Parallel activity and growth especially in the radiographer professional group is also required to ensure the consolidation and advancement of the imaging services which are adopting an increasingly important role in both the diagnostic and therapeutic domains of cancer care services.

Similarly, to the provisions of the Plan for the pathology services, a number of measures have been included to address the requirements for continuous upgrading and updating of the imaging services particularly where it impacts a number of phases in the cancer care services such as screening, detection, localisation, staging, treatment and follow-up. Consequently, some of these measures are analogous to those included for the pathology services and include the:

1. Conduction of regular evaluations to identify requirements for new procurement, replacements and upgrades of equipment for the diagnosis and monitoring of cancers and interventional radiology. Continued investment for the identified requirements and the necessary physical infrastructure needs to be sought and secured.
2. Continuation of activity and effort to ensure the ongoing documentation of the medical quality of diagnostic imaging examinations and the associated descriptions and reporting. Continuous quality assurance requires a culture of comprehensive reporting, supported by tools that help prevent radiology errors and improve communication across care teams. Structured radiology reporting provides a strong foundation for radiology quality assurance, peer review and research.
3. Assurance of sufficient capacity of human resources and expertise within the different diagnostic and therapeutic imaging units to meet the forecasted increase in demand resulting from increasing incidence and expanding sophistication and scope of the applicable technologies (including interventional radiology) through inter alia recruitment, correct staffing and division of tasks, strengthening specialist training and supporting programmes for continued professional education.
4. Preparation and financing of post-specialist educational programmes for imaging in oncology in the fields of ultrasound, CT and MR scanning for radiologists. Plan and implement the necessary structures and processes to introduce post-registration sub-specialisation for radiographers.
5. Provide the support needed to ensure the implementation of the appropriate accreditation processes of the whole imaging department within MDH and especially of the specialised units directly involved in the diagnosis and monitoring of cancer.
6. Provide the support needed to consolidate and further develop processes that allow for double reading for tumour diagnostic and intervention processes (particularly for rare conditions) especially when this requires collaboration with expert radiologists working in centres of expertise abroad.

A2. Improving accessibility to and availability of high-quality services for the treatment of cancer

This sub-section will be further sub-divided into the following:

- A2.1: Maintaining and improving the quality of surgical interventions in oncology
- A2.2: Maintaining and improving the quality of oncological treatments
 - A2.2.1: Radiotherapy
 - A2.2.2: Systemic/ chemotherapy
 - A2.2.3: Paediatric oncology
 - A2.2.4: Rare cancers

A2.1: Maintaining and improving the quality of surgical interventions in oncology

Surgery remains the single most effective modality of cancer treatment and the cornerstone of treatment for a number of cancers (Price, Sikora and Illidge, 2008). Increasingly, it is becoming more conservative as newer techniques are now better able to allow for the retention of organs and structures and in turn capable to maintain good function in many parts of the body. New technology is gradually permitting more minimally invasive (keyhole) surgery for many cancer types and robotic surgery will allow progressively more automated surgical approaches with enhanced effects and minimal damage to surrounding structures.

A major goal of surgical oncology is to remove the cancer together with an area of healthy tissue surrounding it, also known as a clear margin or clear excision, in order to prevent the cancer from recurring in that area (to prevent local recurrence). When the removal of the whole tumour is not possible, surgical techniques may be used to remove as much of the tumour as possible (often referred to as “debulking”) and to relieve symptoms such as pain, airway obstruction, or bleeding. However, the contribution of the surgical oncologist goes beyond what is done on the day of surgery itself. As part of the multi-disciplinary care team, she or he can provide expert opinion on and involvement with biopsy techniques, optimisation of image guidance, the likelihood of achieving clear margins (especially in borderline resectable cases), and what role there is, if applicable, for surgical management of more advanced disease (Bonner Miller, 2016).

Quality surgery is critical to optimise the success rate of other oncological treatments such as chemotherapy and radiotherapy. Surgical determination of the lymph node status (involvement or otherwise) where applicable, can help determine prognosis as well as further treatment options. The types of surgeries that are performed on different types of cancers are dependent on the stage and location of the tumour, cancer cell biology and the fitness of the patient for surgery, and will continue to advance as surgical techniques keep on evolving.

The surgical removal of a tumour can sometimes result in the creation of a defect that could be physically and aesthetically devastating or impact on function. Reconstructive techniques are increasingly being used for certain cancers. These interventions are important especially because of the positive impact that they may have on the patient’s quality of life. Reconstruction can take place at the same time that the cancer is removed, (“immediate reconstruction”), or weeks to months later as in “delayed reconstruction”. “Oncoplastic surgery” refers to surgery when the surgical oncology and reconstruction interventions are performed simultaneously or during the same surgical operation. A common example is the performance of the combined surgical approach of a breast mastectomy with immediate reconstruction.

The surgical treatment of cancer requires ongoing attention and resourcing to allow this important service to continue evolving in line with the dissemination of updated knowledge, techniques and the related emerging advanced technology. Furthermore, apart from the inherent increases in cancer incidence due to the ageing of the population, it is acknowledged that as a result of cancer screening and heightened efforts to increase the likelihood of early diagnosis, more and more patients are being diagnosed at a stage when their disease can be curable with surgery alone and this may further increase the demand for these important services. This has a substantial impact on the central activities for the measurement and monitoring of the waiting lists for oncological surgery procedures with a view to controlling and reducing waiting lists as much as possible. As a result, these processes need to be sustained and further developed.

Consequently, the Plan is advancing the following measures:

1. Intensification of activity to train more surgeons specifically in the specialisation of surgical oncology within the different sub-specialised surgery components (e.g. orthopaedics, neurosurgery, urology, gynaecology, ENT, etc.) and for specific cancer sites (e.g. breast, colon and rectum, prostate). The training of surgeons is a long and expensive process. The complements that we need to aspire to can be guided by the specialist workforce to population ratios recommended in publications such as the regular updates published by the Royal College of Surgeons of England (Greatorex and Sarafidou, 2011). Surgical outcomes have been shown to correlate closely to the number of similar procedures performed by the surgeon - high volume centres generally registering better outcomes for patients. For this reason, we should also work towards identifying and setting up more core groups of specialist surgeons for each tumour site to help improve patient outcomes.
2. Introduction and implementation of more mini-invasive oncology surgery in sectors with recognized scientific evidence. This includes the need to increase investment to amplify inter alia the capacity, through more infrastructure (up-to-date equipment, theatre time) and human expertise (surgeons, supporting medical specialists such as anaesthetists and specialised theatre nurses) in order to augment the output for laparoscopy and endoscopy interventions.
3. Identification of areas with greatest need for development and introduction of more surgical intervention, especially where national cancer survival is substantially below EU average (e.g. pancreas, lung, stomach, oesophageal, kidney cancer) (Baili et al., 2015).
4. Engage in more practices that promote the optimisation of equipment utilisation for the different surgical sub-specialities while providing more dedicated resources for individual sub-specialities including specialised theatre equipment and setups.
5. Ensuring sufficient capacity with regards to human resources and expertise within general surgery and in particular for the increased activity envisaged for laparoscopic, endoscopic, laser-assisted, oncoplastic and other oncological surgery through recruitment, correct staffing and division of tasks, strengthened specialist training and supported programmes for continued professional education.
6. Continuation in the development of new and updating of existing guidelines for surgical treatment, based on the application of best practices covering all the stages from diagnosis, therapy to longitudinal monitoring (follow-up) of the cancer patients.

A2.2: Maintaining and improving the quality of oncological treatments

The majority of non-surgical oncology treatment in Malta (in accordance with the UK) is delivered by clinical oncologists. The UK system is almost unique in that clinical oncologists deliver both radiotherapy as well as systemic therapies in all their different forms. This model of working is considered to facilitate co-ordination and continuity of care and efficient and cost-effective service delivery (Benson, 2015). Frequently, clinical oncologists specialise in the management of specific types of tumours and this will determine the treatments they deliver. The scope of these treatments and their growing complexity, the increase in the number of patients seeking treatment, more patients suffering co-morbidities and the expectation of clinical oncologists to contribute to research and participate in clinical trials are resulting in the need to augment and further specialise the complement of clinical oncologists in order to meet the forecasted increases in the workload and demand for sub-specialist expertise (Benson, 2014).

Another important speciality in oncological care is haematology or clinical haematology. Haematologists investigate, diagnose and treat diseases such as anaemia, patients with blood-clotting abnormalities and malignancies of the blood, bone marrow and lymphatic system such as leukaemia, lymphoma and multiple myeloma (haemato-oncology). They also care and are responsible for ensuring the availability and safety of blood transfusions when needed. The work of the professionals in this medical speciality encompasses both clinical and laboratory practice. As a result of this dual role, haematologists take an active part in every stage of patient management, from the initial clinic visit, to laboratory assessment and diagnosis and finally to treatment and follow-up. Different levels of service are needed to manage haematological cancers, depending on the particular cancer in question. As in clinical oncology the increasing complexity of care and changes in the level of care requires the consideration of expansion and further sub-specialist services (National Institute for Health and Care Excellence, 2016).

The clinical oncology and haemato-oncology services require the multi-disciplinary involvement of a wide and diverse group of highly specialised allied healthcare professionals (particularly rehabilitation specialists, clinical psychologists and dieticians), clinical pharmacists and clinical nurse specialists and also the close support of the hospital administration and other hospital specialities such as diverse pathology specialities (especially microbiology, virology and infection control), intensive care facilities and specialist palliative care (Royal College of Pathologists, 2015).

A2.2.1: Radiotherapy

Radiotherapy can be conventionally delivered using external beams therapy (EBRT) or by brachytherapy (placing a radioactive source in close proximity to or inside the tumour) depending on the clinical indications. New methods of delivery and additional scope of treatment with radiotherapy are also emerging and include molecular radiotherapy (MRT) which involves the use of injected or ingested radio-isotopes, proton beam therapy (PBT), adaptive radiotherapy based on advanced imaging (such as MR-LINAC) and stereotactic ablative body radiotherapy (SABR). Recent advances in radiotherapy using cutting-edge imaging and computing technology (such as VMAT, IMRT and IGRT⁴) have helped to target radiation doses more precisely. Apart from delivering better outcomes, these improve the quality of life of patient and can reduce long-term costs to the health service because patients suffer from less side-effects of radiotherapy. Radiotherapy can be administered separately, sequentially or concomitantly (chemo-radiotherapy) with systemic therapy depending on the clinical situation.

Radiotherapy is the most clinically and cost-effective non-surgical treatment available to cancer patients. This modality of treatment is required by 45-55% of all newly diagnosed cancer cases (Datta, Samiei and Bodis, 2014). Treatment with radiotherapy can contribute to the cure of an estimated 40% of cancer patients (Hiom, 2015), (Freitas and Weller, 2015). Additionally, radiotherapy also improves quality of life through rapid and effective symptom control.

With the migration of the oncology services to the new Sir Anthony Mamo Oncology Centre (SAMOC), and the commissioning of new Linear Accelerators (LINACs) it has become possible to develop the delivery of a number of advanced radiotherapy techniques in Malta. The development and implementation of a number of

4. VMAT = Volumetric Modulated Arc Therapy; IMRT = intensity modulated radiation therapy; IGRT = Image Guided Radiation Therapy

these techniques for specific cancer sites is already underway in collaboration with the technical assistance of the Leeds (Cancer Centre) Teaching Hospital NHS Trust and the International Atomic Energy Agency (IAEA).

The Plan has included the following measures to assist in the consolidation of this activity, embark on further development over the next few years and meet incoming European Union⁵ standards and directives:

1. Upgrading of the LINAC machine brought over from the old oncology facility so that it can also be used for some of the services possible with the newer machines.
2. Procurement of the required additional and accessory equipment to the new LINAC setups so that more advanced radiotherapy treatments can be delivered and the associated and essential quality assurance procedures can be further developed and regularly conducted.
3. Commissioning a needs analysis and the initiation of the resultant required investment in preparation for the introduction of brachytherapy treatments in Malta.
4. Upgrading and sustaining the necessary ongoing recruitment to continuously increase in the complement of radiographers and medical physicists specialised in radiotherapy engaged at SAMOC. The health work force comprising these two highly specialised groups of professionals has been substantially boosted over the past few years. However, the total complement is still below that necessitated by the current volume of services offered and these needs will continue to increase due to the increasing demand and the introduction of more sophisticated radiotherapy treatment modalities and techniques. These include the recruitment of more medical physics experts and a radiation protection expert for the radiotherapy services provided at SAMOC.
5. Preparation and regular updating of good practice guidelines on a national level for radiotherapy treatment techniques and the indications for the use of radiotherapy, and for the introduction of relevant accreditation processes for selected sectors and/ or processes performed by the radiotherapy department. Consolidation of existing and further application of new quality assurance mechanisms including the concurrent investment that these require.

A2.2.2: Systemic/ chemotherapy

Chemotherapy and other systemic therapies have a vital role in the treatment of cancer. They also play a critical role in combination with other treatment modalities, for example by helping to reduce the volume of tumour masses so that they can be more successfully removed and targeted with surgery or radiotherapy.

Systemic therapies can be delivered with an ever-increasing wide range of drugs and include chemotherapy and endocrine therapy or hormone therapy. More recently, targeted biological therapies such as antibodies, small molecules and immunotherapy are systemic treatments that are progressively gaining more prominence. With the increasing awareness and knowledge generation on tumour heterogeneity and the ever-expanding complexity of novel targeted therapies and combinations of therapies, this branch of oncology is expected to continue to undergo profound changes in the next few years (Freitas and Weller, 2015).

5. Requirements as per COUNCIL DIRECTIVE 2013/59/EURATOM of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/EURATOM, 90/641/EURATOM, 96/29/EURATOM, 97/43/EURATOM and 2003/122/EURATOM. Directive to be transposed into MT legislation by February 2018.

Drugs for cancer treatment and their rapid uptake are important for providing modern and advanced treatment options for cancer patients. Comparative assessments of system approaches to the organisation and funding of cancer care and especially cancer drugs show wide variations in the uptake of these drugs and especially new innovative cancer medicines across countries. A major recognised contributor to these differences is the high costs associated with cancer treatments (Nolte and Corbett, 2014). Expenditure on the procurement of cancer drugs was found to account for 0.1-2.4% of the total health expenditure across countries, according to the data collected through the OECD Healthcare Quality Indicators (HCQI) Questionnaire on Systems of Cancer Care. Given that cancer care costs amount to about 3-7% of total expenditure, these costs actually comprise a considerable proportion of the total spending in cancer care systems (Organization for Economic Co-Operation, 2013).

The pathway involved in the authorisation and the actual provision of access to new drugs to cancer patients involves several processes that usually includes marketing authorisation, health technology assessments or HTAs (usually involving an evaluation of the clinical efficacy/effectiveness and cost-effectiveness of pharmaceuticals), and processes that lead to the inclusion of new drugs on the positive lists (the Government Formulary List – GFL, in Malta), protocol setting for reimbursement or free financial access and for price negotiation and actual procurement. This pathway has been shown to lead to considerable ‘drug lags’ (delay in making the drug available to a patient once it is authorised) between and within countries) (Greatorex and Sarafidou, 2011), (Jönsson and Wilking, 2007).

The debate about differences in the availability of cancer medicines across nations and the cost of cancer treatment has prompted considerable public debate in several countries, including Malta. A number of countries including Australia, Germany and France have put in place separate funding mechanisms to ensure access to cancer drugs and especially innovative cancer medicines such as the Cancer Drugs Fund introduced in England in 2010 with variable success (Chamberlain et al., 2014). Health systems need to continue seeking economically feasible solutions that can ensure that patients have routine access to a greater range of cancer drugs, including earlier access to innovative drugs, while ensuring that cost-effectiveness is maintained (Harpal, 2015).

To address the important issues associated with the delivery of systemic therapy and especially the substantial impact on the national health systems to ensure the availability of approved, clinically- and cost-effective cancer drugs, the National Cancer Plan is including the following actions:

- 1. Continue to identify and secure new funding streams and procurement methodologies to ensure the sustained procurement of cancer drugs that have completed the whole process of evaluation and have been approved for inclusion onto the GFL.**
- 2. Invest in the specialist and/ or post-specialist training programmes and opportunities for the professionals working in the cancer care services that are responsible for the delivery of conventional chemotherapy and emerging systemic therapies. Establish an expert working group to monitor emerging evidence and advice on the use of immunotherapies and other targeted biological therapies for different types of cancer, considering the implications for financing, roll-out and workforce.**
- 3. Strengthen the capacity of the structures that are responsible for the appraisal of new drugs for safety, clinical- and cost-effectiveness (HTAs) and the structures for the approval and addition of new cancer drugs on the GFL and the procurement processes of these drugs. This will entail the engagement, retention and**

training of the required expert human resources and the necessary support to sustain and further develop their essential networking functions with similar institutions working in other countries.

4. Design and implement national clinical guidelines for the delivery of systemic treatment of a number of selected cancer sites, uniform documentation (including electronic prescribing) and strengthen the monitoring of the use and timely delivery of cancer drugs and the outcomes of patients receiving these therapies.

A2.2.3: Paediatric oncology and cancer in adolescents and young adults (AYA)

Cancers in children and young people are rare but it is nonetheless a major health issue. In Malta, about 25 children, adolescents and young adults (up to the age of 24) are diagnosed with cancer each year. These cancers can be quite different from cancers affecting adults and they tend to occur in different parts of the body to adult cancers. They also look different under the microscope and respond differently to treatment. The most common cancers in children (up to age 15), in descending order are leukaemia, brain and spinal tumours, lymphomas, soft tissue sarcomas and neuroblastomas (together amounting to 80% of all childhood cancers) (Children's Cancer and Leukaemia Group, 2015). On the other hand, teenagers and young adults (15-24 years) tend to get different types of cancers to children and adults, with the most common ones being lymphomas and carcinomas, germ cell (ovarian and testicular) and brain and central nervous system (CNS) tumours (ibid.). Figure 10 shows the common types of cancers diagnosed in Malta in children, adolescents and young adults between 1994 and 2014. Males were more often affected than females (M: F ratio = 4:3). The average number of new cases per year over the period 1994 to 2014 (21 years) was larger for the 15 to 24 year age group (13.5) than for the 0 to 14 years age cohort (11.9).

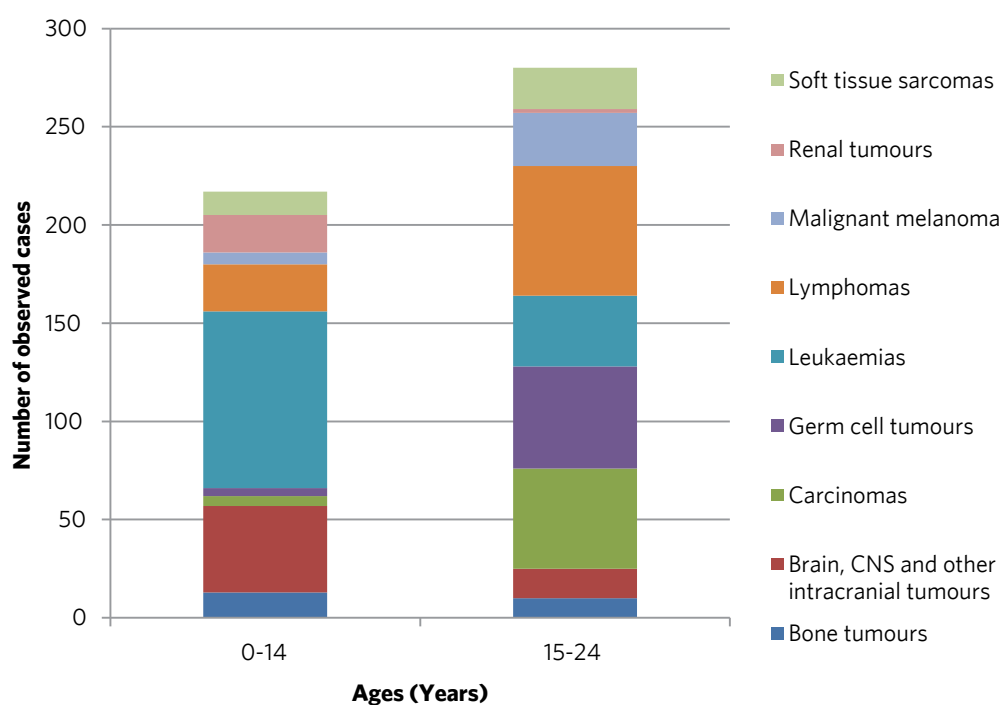


Figure 10: Common types of cancer diagnosed in Malta in children, adolescents and young adults (0-24 years of age) between 1994 and 2014

Source: Malta National Cancer Registry, Directorate for Health Information and Research, Ministry for Health (2016).

Cure rates for children are much higher than for most adult cancers. The survival rate for childhood cancer has more than doubled since the 1960s. On average, as shown in Table 9, more than 80% of all children diagnosed with cancer can now be cured (taken as 5-year relative survival). For some types of childhood cancer, the cure rate is much higher.

	Malta	Europe
All Cancers	81.2 (72.1-87.9)	78.4 (76.2-80.1)
CNS	61.2 (29.4-82.1)	57.7 (52.3-62.5)
All Cancers without CNS	83.7 (73.1-80.2)	82.1 (80.1-84.1)
Acute lymphocytic leukaemia	92.1 (81.8-99.1)	86.4 (83.1-89.2)

Table 9: Paediatric cancers (0-14 yrs) - 5-yr relative survival. Patients diagnosed in 2000-2007 and followed up till end of 2008 - EUROCARE-5 Study (Gatta et al., 2014)

Despite improving survival rates, cancer is still an important cause of death by disease beyond one year of age as shown in Tables 10a and 10b. However, it is noticeable that the proportion of deaths from neoplastic disease to all deaths caused by medical causes has markedly decreased between the 5-year time ranges of 2001-2005 and 2011-2015 for both the childhood and the AYA age groups.

	age group 1-14 years			
Cause of death	2001-2005 (N)	2001-2005 (%)	2011-2015 (N)	2011-2015 (%)
Neoplasms	16	33.3	6	23.1
All other disease causes (excluding accidental or violent deaths)	32	66.7	20	76.9

Table 10a: Deaths from neoplasms compared to deaths from all other disease causes in the 1-14 year age group over two 5-year periods

	age group 15-24 years			
Cause of death	2001-2005 (N)	2001-2005 (%)	2011-2015 (N)	2011-2015 (%)
Neoplasms	22	37.9	13	30.9
All other disease causes (excluding accidental or violent deaths)	36	62.1	29	69.1

Table 10b: Deaths from neoplasms compared to deaths from all other disease causes in the 15-24 year age group over two 5-year periods
Source: National Mortality Registry, Directorate for Health Information and Research, Ministry for Health, Malta (2016)

The improving survival rates have resulted in an increasing number of childhood cancer survivors and it has been estimated that two-thirds of these young people develop late side-effects of treatment. These can impact on the daily life and future prospects of a substantial proportion of those affected (European Society for Paediatric Oncology, 2015). Furthermore, cancer survivorship can impact a wide variety of issues such as follow-up and future care; fertility, lifestyle, feelings and emotions; and individual plans for further education, employment and equal opportunities, travel, life insurance and bank loans (National Institute for Health and Care Excellence, 2016).

The two principal objectives for further development in the management of cancer in children and AYA (adolescents and young adults) are to increase the cure rates and improve the quality of survivorship (European Society for Paediatric Oncology, 2015).

This National Cancer Plan includes the following measures aimed at addressing these main objectives:

- 1. Conduct a review of the national operations in Paediatric Oncology guided by international standards such as those established by the Society for Paediatric Oncology Europe (SIOPE). Review to concentrate on:**
 - i. volume effect in paediatric oncology**
 - ii. staffing challenges and educational opportunities (incorporating the needs of and as an integral part of both the Paediatrics Department at MDH and the Paediatric Oncology Unit within the Oncology Centre (SAMOC).**
 - iii. core elements for adequate paediatric cancer treatment and support services. The issues concerned with the transition of young patients from the paediatric to adult oncology services require special attention.**
 - iv. social care aspects (including continuous education during treatment)**
 - v. the role of parents and patient organisations**
 - vi. methods and tools for integrating standards into national guidelines.**
- 2. Promote the specialisation in Paediatric Oncology particularly with specialist trainees in paediatrics.**
- 3. Advocate for and implement measures to increase activity in research collaborations including the involvement of a gradually increasing proportion of our young patients in clinical trials.**
- 4. Address the special needs of young cancer patients and cancer survivors, in particular through the involvement and education of their parents and through the elaboration of careful survivorship plans that address the social, educational and long-term implications of surviving cancer from a young age. Advocacy with relevant stakeholders such as employment and social security services requires renewed impetus.**

A2.2.4: Rare Cancers

Views of what makes a type of cancer rare differ. However, generally, cancers are considered rare if:

- They start in an unusual place within the body
- The cancer is an unusual type that may need special treatment. Examples can be rare sub-types arising in common cancers sites such as angiosarcoma or lymphoma of the breast. The growing prominence of molecular diagnostics is enabling the differentiation of more subsets of rare cancers within the broader categories of frequent tumours and that are responsive to targeted therapies.
- Fewer than 2-6 in 100,000 people are diagnosed with the specific cancer type each year (Cancer Research UK, 2014)⁶.

6. There is no internationally agreed definition of rare tumours. In the RARECARE project they have been defined as those cancers with an incidence of M 6/100,000. Available at: <http://www.rarecare.eu/default.asp> (Accessed: November 2016).

Around 200 different types of rare cancers have been identified. Collectively they represent about 22% of all cancer cases diagnosed in the EU28 each year, including rare adult solid tumours (13%) and rare haematological cancers (8%) as well as all childhood cancers (1%) (Surveillance of Rare Cancers in Europe, RARECARE).

A number of specific challenges both for the cancer patient as well as for the health system involved are posed by the singularity of most of these low frequency tumours. These include:

- i. Late or incorrect diagnosis
- ii. Lack of access to appropriate therapies and clinical expertise
- iii. Very limited number of clinical studies due to the small number of patients
- iv. Lack of interest in developing new therapies due to limitations in the market
- v. Few available registries and tissue banks (Surveillance of Rare Cancers in Europe, RARECARE).

Frequently, the management of cancer patients diagnosed with rare cancers in Malta involves their referral to centres of expertise overseas for diagnosis and/ or treatment. In fact, on an annual basis near to 50% of all referrals through the National Highly Specialised Overseas Referrals Programme are for cancer patients diagnosed with different types of neoplastic disease and most of these can be classified as low frequency tumours.

The Plan is advancing the following measures to better address the challenges posed by rare tumours especially because of the complexity of the diagnostic and therapeutic processes involved:

- 1. Follow-up and participate in ongoing activities at EU-level in the field of Rare Cancers.**
- 2. Seek to further develop systems for the transfer of specialised knowledge and expertise needed for the improved management of people diagnosed with different forms of rare cancers. Specialised knowledge and expertise is required for several phases of the cancer care pathway of these patients including the after-care phases following their return from treatment abroad.**
- 3. Ensure sustainability and growth (as required) of the referral systems that involve the transfer of patients abroad for diagnosis and treatment in specialised centres of expertise in the UK and elsewhere.**
- 4. Follow the development of and seek to participate as necessary in relevant European Reference Networks managing different groups of patients with rare tumours.**

INDICATORS FOR SECTION A

Type of Indicator	Indicator
Structure	<ul style="list-style-type: none"> Primary Healthcare resources (equipment, professionals/ expertise and activity, per population) Pathology resources especially cellular pathology (equipment, professionals/ expertise and activity, per population) Imaging and nuclear medicine (equipment, professionals/ expertise and activity, per population) Surgery especially surgical oncology (equipment, professionals/ expertise and activity, per population) Clinical Oncology resources (equipment, cancer drugs, professionals/ expertise and activity, per population) Paediatric Oncology resources (equipment, cancer drugs, professionals/ expertise and activity, per population) Resources for molecular genetic analysis Genetic counselling services Existence of regularly updated evidence-based, multidisciplinary clinical practice guidelines by tumour site
Process	<ul style="list-style-type: none"> Clinical outputs by specific types of intervention/ activity, e.g. number of histologies reported, number of US/ CT guided biopsies, number of breast surgeries with immediate reconstruction, number of radiotherapy sessions Interval of time between symptom suspicion/referral by a physician detection and confirmation of the diagnosis (patient and healthcare/system provider factors) Delays in treatment delivery: surgical procedures, chemotherapy and radiotherapy treatments (disease and healthcare/ system factors) Multidisciplinary teams: % of patients' coverage by tumour site Collection of specific population-based information/databases on diagnosis and treatment of cancers diagnosed in childhood, adolescence and young adulthood and rare tumours Users' views on the quality of information and communication received along the cancer care process, with a special emphasis on assessing continuity of care
Outcome	<ul style="list-style-type: none"> Survival rates by tumour site and according to the stage in the diagnosis if available (1-, 5- and 10-year survival) 30-day post-operative mortality rate and/or re-admission rates for complex surgical procedures performed for curative purposes e.g. for oesophageal, stomach, pancreatic, rectal and lung cancers and for neuro-oncology and liver metastasis Rate of recurrence of by cancer site Perceived satisfaction from patients along the cancer care pathway

B. IMPROVING THE QUALITY OF LIFE OF CANCER PATIENTS

Greater understanding of the human needs of cancer patients is progressively increasing and focusing attention on previously neglected areas of care such as patients' psychosocial needs and care at the end of life and other areas that are emerging and gaining in importance primarily as a result of the increasing rates of survival after diagnosis and treatment and consequently increasing expectations that patients return as much as possible to their levels of economic and social activities prior to their diagnosis.

This section will be further sub-divided into the three following sub-sections:

- B1. Survivorship and rehabilitation
- B2. Psychosocial oncology care
- B3. Palliative and end-of-life care

B1. Survivorship and Rehabilitation

Despite the decline of cancer mortality rates in developed countries, incidence and prevalence rates are still increasing, leading to a growing population of people living with or beyond cancer². The concept of survivorship goes beyond patients who are fully cured and encompasses various situations people have to face after the completion of the active treatment period such as patients:

- who are in remission or fully cured and would need to return to normal activity;
- with recurrence after a prolonged period of remission who may receive new courses of treatment with a curative intent;
- who live with incurable cancer as a "chronic disease" and receive life prolonging treatment.

Therefore, the challenges for health care policy and cancer survivorship planning need to incorporate both the objective of "how long" people live after diagnosis as well as "how well" people can expect to live from diagnosis onward. Consequently, the focus is progressively shifting towards the expectations for the quality of survival both after curative treatment and while living with recurrent disease.

The World Health Organisation defines "rehabilitation" as "a process aimed at enabling them [people with disabilities] to reach and maintain their optimal physical, sensory, intellectual, psychological and social functional levels" (World Health Organisation, 2015). This definition has its roots in the WHO definition of health as "a complete state of physical, mental and social well-being, and not merely the absence of disease or infirmity". Rehabilitation aims at recovering health and well-being after an injury or disease by enabling individuals with proper assistance and tools in restoring their quality of life, and ability to live independently, and participate in education, the labour market and civic life.

Rehabilitation services require the involvement of various disciplines of Allied Healthcare Professionals (AHCP). This support includes physiotherapy, occupational therapy, speech therapy, and expert dietician advice. Early access to rehabilitation advice can reduce acute visits to hospital, and specialised clinics such as pain clinics, as well as enabling patients to return home more quickly after treatment.

Dealing with survivorship and rehabilitation service requirements is a relatively new notion in cancer policy and several countries are still grappling with the issues of starting to develop policy and strategy stances of how to respond to these 'new' demands. Emerging knowledge and demonstrated good practice are recommending a number of strategies to help address the complex issues associated with cancer survivorship (Albrecht, Kiasuwa and Van den Bulcke, 2017).

This National Cancer Plan will be promoting a number of these recommendations with a view of developing an effective national program in this domain. The main guiding principle is to embed rehabilitation and survivorship care plans throughout the continuum of care, from the onset of the disease. Most of these services can be of benefit to a wide range of cancer patients and not only cancer survivors.

1. The follow-up of cancer survivors, the management of the late effects of cancer and cancer treatment (there can be direct and indirect effects on physiological, psychological and interpersonal factors that can negatively impact the future health and well-being of cancer survivors) and tertiary prevention (early detection of cancer recurrence) need to be anticipatory, personalised and implemented by means of care pathways, with active participation of survivors and their relatives and healthcare professionals especially in the community setting and family doctors in particular. Progressing on this objective requires the:

- i. allocation of adequate resources: financial and human (numbers and expertise).
- ii. use of digital methods (e-health supports) to facilitate the sharing of information between the patients and care providers.
- iii. consideration of a new role for a clinical oncologist with special interest and access to specialised training in survivorship - to treat long-term effects of chemo/ radio-therapy in survivors.
- iv. networking between professional experts on specific late effects, such as post-radiation neurotoxicity or drug-related impaired immune function, to facilitate their identification and management, and support the family practitioners. Data collection and research needs to involve and be taken up by both the networking experts as well as the family doctors.

2. Pursuing improvements in the early detection of patients' needs and access to rehabilitation, psychosocial and palliative care services as soon as these are indicated. Special attention will be given to:

- i. screening for psychological distress and psychosocial needs which should be conducted periodically during the entire cancer pathway and integrated in the care provided by oncologists, nurses and primary care professionals. Positive cases need to be referred to and followed up by psychosocial care which is led and coordinated by appropriately trained professionals with specific expertise in psychosocial oncology.
- ii. provision of social rehabilitation services and identification of return-to-work issues. The adaptation of the working conditions for any patient returning to her/his previous work and/ or social engagements should be assessed at early stages. The working lives of cancer survivors, their employability, competencies and capacity to work, as well as their motivation to work need to be safeguarded and when necessary the attainment of new skills is facilitated. Survivors may need help to achieve the most advantageous balance between their health needs and employment such as flexible working hours and models. Assistance could also be sought from patients' organizations, employers and trade unions (e.g. provision of rehabilitation coaches and providing patients with more information and befriending activities).
- iii. supportive and palliative care: *(these measures will be described and discussed in more detail in the next section).*

3. An integrated and multi-disciplinary care approach with a coordination of community care providers and services as well as the empowerment of survivors are needed to implement a Survivorship Care Plan (SCP). This plan is ideally elaborated and implemented by the treatment team with the essential participation of the family doctor. Increasing evidence from the literature is pointing towards four good practice models:

- i. the family practitioner or primary care team should play an important role in patients' follow up;
- ii. the follow-up model should provide for rapid re-entry channels to systems to specialised cancer care, when required.
- iii. a healthcare professional should assume the role of a coordinating case manager or navigator (see sub-section A1.1) by being a point of reference and contact for the patient and the team.
- iv. development of the necessary infrastructure and resources for community based outreach programs (Albreht, Kiasuwa and Van den Bulckle, 2017).

The empowerment and education of patients and their relatives will be given more prominence. Through a person-centred approach, this will aim at increasing the patients' participation in self-management programs, in rehabilitation and back-to-work programs and ultimately in giving them more person control over the process.

5. Special cancer survivorship care issues for survivors of cancer diagnosed and treated in childhood, adolescence and early adulthood. Some of these issues have also been presented in sub-section A2.2.3 dealing with paediatric oncology and cancer in adolescents and young adults (AYA). The specific potential health (e.g. secondary malignancies and increased risk for cardiovascular disease) and psychosocial consequences (these may appear several years after the cancer is cured) of cancer and its treatments in these age groups need to be better anticipated and addressed. Measures will try to achieve improvements in the transition of care from paediatric oncology to adult medicine to guarantee adequate long-term follow-up and the development of appropriate interventions. A 'survivorship passport' for each patient could be considered (European Society for Paediatric Oncology, 2013). A routine (e.g. annual) psychosocial assessment with attention to social, psychological, and behavioral issues, educational and/or vocational progress should be provided to this population.

6. More cancer research and coordination of research is needed to study the added-value and cost-effectiveness of services that cater for survivorship, rehabilitation, supportive, palliative and psychosocial care interventions. Modalities that can impact activity in this area include cancer registries (by collecting more data on survivors); collection of patient reported outcomes and clinical research that evaluates the feasibility, efficacy, cost-effectiveness and health economics of these care services as well as non-drug related interventions such as self-management and the use of e-health tools.

B2. Psychosocial oncology care

Cancer and its treatment have a significant impact on the quality of life of patients and their families and carers. A substantial proportion of cancer patients and survivors can experience high levels of cancer-related distress (Carlson, 2004), and may develop more serious mental health problems such as adjustment disorders, anxiety disorders and depression (Mitchel, 2013). These conditions can negatively impact on clinical outcomes such as treatment compliance, survival and quality of life and may require specialised psychosocial care (Grassi and Travado, 2008). Psychosocial problems also affect the patient's family with a consequent increase in emotional distress among the patient's caregivers. These psychological problems may continue into the bereavement period, with greater risk of complicated or traumatic grief among relatives. Patients' and their family supportive care needs must be an important component of quality comprehensive cancer care (Martin-Moreno, 2015).

Psycho-oncology addresses a range of psychosocial, behavioural, spiritual and existential dimensions that the patient and family face throughout the cancer care continuum. A primary goal of this domain is concerned with the target that all cancer patients and their families receive the best possible psychosocial care at all stages of the disease and into survivorship (Grassi and Travado, 2008).

Despite the major implications of psychosocial morbidity for clinical care, psychosocial issues in cancer are still all too often dismissed or underestimated. The significance of the psychosocial aspects of cancer and its treatment is growing in importance owing to the growing numbers of cancer survivors (Coleman et al., 2008).

The main aim of the Plan in the field of psychosocial oncology care is to advance the recognition of the importance of this domain in the cancer care services in Malta. The following measures will be pursued in order for the scope of and capacity for psychological oncology care to expand and to start meeting the hitherto by and large 'unmet needs' of patients and their caregivers.

1. Training of healthcare professionals working in close contact with cancer patients in psychosocial aspects and communication skills: training in communication skills contributes to better patients' clinical outcomes and can reduce workforce burnout (Albrecht, Kiasuwa and Van den Bulcke, 2017). Promoting effective communication between patients, caregivers and healthcare professionals can be achieved through:

- i. the continued inclusion of training in communication skills training in undergraduate and postgraduate curricula for physicians, nurses, and allied health care professionals in all care and in cancer care in particular;**
- ii. continued professional development programmes in psychosocial oncology in all cancer care settings.**

2. Screening for Distress and assessment of psychosocial needs: distress is an unpleasant emotional experience of a psychological, social and/or spiritual nature which extends on a continuum from normal feelings of vulnerability, sadness and fears to disabling problems such as depression, anxiety, panic, social isolation and spiritual crisis (Martin-Moreno et al., 2015). The International Psycho-Oncology Society (IPOS, 2016) promotes the measurement of distress as the 6th Vital Sign (the other five vital signs are temperature, blood pressure, pulse, respiratory rate and pain). The application of a number of methods for screening for distress have been developed, tested, and validated in many countries worldwide such as the Distress Thermometer, the Edmonton Symptom Assessment System and the Canadian Problem Checklist (Carlson et al., 2012), (Bultz et al., 2011). Addressing the often-neglected aspects of patients' and their families' psychosocial needs should be routine in clinical practice as there is evidence that this has positive benefits for patients' clinical outcomes, can be used as an endpoint of cancer care and provides a useful indicator of the quality of performance of the care services (Travado, 2006).

3. Employment of evidence-based treatments for symptoms and psychosocial needs and development and implementation of psycho-oncology services, minimum practice standards and integration in multidisciplinary teams: a wide range of psycho-oncology approaches and treatments such as educational and psychological support interventions, counselling, coping skills and psychotherapy (individual, group or family) can be employed. Survivorship classes wherein patients are coached and mentored to develop coping skills that will help them to navigate through difficulties arising from surviving cancer will also be planned. These initiatives require the engagement of professionals with expertise in psycho-oncology in the multi-disciplinary treatment team (MDT). An assessment of the psycho-oncology care needs to be undertaken to determine the capacity of the services required (number of professionals and level of their expertise according to the number of cancer patients - new cases and prevalent cases) and an action plan will be drawn up to establish the resources required and how and by when they will be acquired.

Children are likely to have very different presentations of psychosocial symptoms and morbidity from adult cancer patients (Martin-Moreno et al., 2015). An important overall consideration is the growing demand for and the need of differentiation and provision of specialised services to support to paediatric cancer patients and their families and childhood and other young cancer survivors.

B3. Palliative and end-of-life care

Palliative care is an essential component of cancer care. Palliative care is often and erroneously only associated with cases of advanced cancer. However, WHO recommends that palliative care should begin early in the course of the illness, thus forming part of the overall intervention protocol (World Health Organisation, 2003). Despite extensive efforts to prevent and cure cancer, the average five-year survival from cancer only reaches between 50% and 60% in the most affluent states. Additionally, several cancers such as oesophagus, pancreas and lung have much poorer survival rates (Coleman et al., 2008). This is compounded by often complex health needs due to the fact that people with cancer and (their caregivers) are frequently and increasingly elderly people with associated problems of co-morbidity.

Palliative care is an approach that improves the quality of life of patients and their families facing the problems associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and assessment and treatment of pain and other problems such as fatigue, anorexia, nausea and constipation. Palliative care is not exclusive to cancer patients and also incorporates psychological and social care to patients and their loved ones throughout the course of the care process, including spiritual services that are tailored to the individual's personal beliefs and/or religious affiliation, especially in the context of end-of-life care (Martin-Moreno et al., 2015).

Several patients would stand to benefit from much earlier access to palliative support in their cancer treatment journey than what is generally provided. Indeed, palliative care needs and support should be considered as soon as a cancer diagnosis is made. Palliative support is often considered secondary to the primary treatment course, despite evidence showing that early referral to palliative care can result in better quality of life, reduced symptom burden, less exhaustive care, and ultimately lower costs for the healthcare services (Pivodic et al., 2015). In reality, the transition from radical, intensive treatment to a phase of less active life-prolonging treatment and palliative care remains poorly understood (Coleman et al., 2008).

Patients with advanced cancer can experience profound symptoms including emotional, social and spiritual consequences associated with cancer, disability and facing the end of life. Unless alleviated, these symptoms can result in great suffering and distress for the patients themselves, their family and those close to them (Davies and Higginson, 2004). Effective support, communication and care is required and indeed these services may need to be available even beyond the death of the patient as the effects on the family can continue long into bereavement, consequently affecting their subsequent health and well-being.

The importance of palliative care as an essential component of cancer care needs to be better acknowledged. A strategic shift needs to be undertaken that necessitates an upsurge in investment in the palliative care domain to increase the capacity of service provision, the diversity and reach of the palliative care services offered especially outside the hospital setting, the scope of education and research in palliative care. All these objectives are necessary if we aspire to achieve the potential of palliative care in order to improve the quality of care for cancer patients and their families, and to help them live well until they die, as well as to die well (Coleman et al., 2008).

In congruence with the above, this National Cancer Plan is advocating for an intensification in the attention that is given to palliative care in comparison to what has been given so far. This amplification requires accessibility to relevant data which is often challenging to attain since information on the structure, process and outcomes of the palliative care phase is often still outside the “main stream” practices for healthcare data collection. Therefore, the inception, identification and consolidation of new and additional sources of information needs to be sought.

1. Establishing and demonstrating the need for palliative and end-of-life services. A ‘needs assessment’ on a national level is a prerequisite. The present specialist palliative care services which are concentrated at SAMOC can only provide their expert services to a restricted number of the cancer patients that require these services. The volume and extent of ‘unmet need’ should be determined for both cancer patients as well as for non-cancer patients so that the upgrade in the resources and expertise required across the whole span of the healthcare services can be better estimated, planned, requested and obtained.

2. Palliative care services can be offered in a variety of settings (hospital-based; hospice; community-based whether in a private home or residential facility such as nursing homes) and modalities (in-patient; day care; out-patient; home-based care or a combination of these modalities). An assessment of the resources required to meet the current unmet and forecasted increase in demand in each of the above settings and modalities is required and needs to also entail an analysis of the roles and interactions between the groups of service providers involved as these need to be better developed and sustained. A more coherent organisation of all service settings and modalities is needed with the aim that care is truly multi-disciplinary, fragmentation is mitigated, efficiencies and cost-effectiveness of services is optimised and continuity of care is guaranteed.

3. Palliative care services entail the management and use of different types of medicines (including opioids), medical devices that include devices needed for the administration of these medicines outside healthcare facilities and equipment needed to help in the execution of activities for daily living (such as wheelchairs to aid mobility) and the management of patients (such as hydraulic beds). The volume and diversity of these resources need to constantly grow to ensure accessibility and availability consistent with the present extent of ‘unmet need’ and also the forecasted increases in the demand for them.

4. Availability of human resources: in terms of quantity, diversity, competence and whether they are hospital- or community-based. This requires the consideration of issues such as recruitment, retention and the provision of opportunities for career progression of staff from a wide range of professions (health and non-health such as social workers) and specialised and/or generic training in palliative care, certification and continued professional development and assessment. Training in palliative and end-of-life care necessitates a generally stronger impetus and presence at all levels of professional training, including:

- i. Providing for opportunities for specialisation, employment and career development in the palliative care speciality. These specialists are essential for the advancement of service standards and also for the provision of support to other professionals working with cancer patients especially in the community;
- ii. Increasing the visibility of palliative care in undergraduate and post-graduate curricula, and continued professional development programmes for all doctors, nurses and allied health care professions;

- iii. The training of professionals working in the primary health care and community care services, particularly doctors in family medicine (general practitioners);
 - iv. The training of oncologists and other professionals working in regular and close contact with cancer patients. More specific and intense training in this field is required.
5. The recognition of the role of volunteers and voluntary organisations. They often have important roles in increasing service provision and mobilising local support and community representation. It is important to ensure quality through careful selection, induction, training, supervision and support.
6. Provision of support and respite to the relatives and other carers attending to patients in their homes and communities. Home carers have a crucial role to play in helping patients remain at home for as long as possible and to as much as possible preserve the psychosocial wellbeing of the patient.
7. Services need to be adapted to be more effective and specialised to deal with different and special groups of patients and circumstances particularly with paediatric and adolescent/ young adult patients. Female and male patients may also require different services and approaches which in part may be related to the traditionally increased propensity for women to assume roles in family care, especially when there are health problems.

INDICATORS FOR SECTION B

Type of Indicator	Indicator
Structure	<ul style="list-style-type: none"> Integration of survivorship and rehabilitation in cancer care services and the health-care system Cancer prevalence Availability of specialised survivorship clinics especially for young cancer survivors Existence of the psychosocial care services/ units in the national healthcare system Number of psychosocial care professionals working in cancer care services and access to/ availability of post-graduate courses and/or MSc courses in psycho- oncology Availability, recruitment and retention of healthcare professionals specialising in palliative care services Inclusion of communication skills training in under- and post-graduate curricula and continued professional development programmes for medical doctors, nurses and AHCPs Diversity of settings providing and modalities offered for palliative care services Doctor and nurse ratio per patient Proportion of healthcare budgets available for and used in survivorship, rehabilitation, psychosocial, palliative and end-of-life care funds for cancer Research activity/ conducted in all the above
Process	<ul style="list-style-type: none"> Availability of surveillance for and treatment to prevent and manage recurrence and secondary malignancy Assessment of surveillance for and management of symptoms and late effects of cancer treatments Perceived quality of life (QoL) of cancer patients before and after rehabilitation support (measured at regular intervals) Qualified prevalence (number of patients at an exact date who have had recurrence, metastasis, other tumours or totally recovered) * Availability of rehabilitation services for specific cancer sites Availability and diversity of rehabilitation service resources in proportion to the volume of patients needing/accessing these services * Proportion of cancer patients that are screened routinely and on a regular basis for distress against the number of cases of cancer per year Place of death of cancer patients Admissions/ referral to palliative care services especially in the last 1 year of life Formal inclusion of palliative care as a medical and nursing speciality Availability of services and resources for the special paediatric and AYA palliative care sector National use of opioids in palliative care; annual number of patients treated, amount prescribed and dispensed, modality of delivery of opioids, list of indications for prescribing opioids. Description of the bureaucratic process for the prescription and dispensing of opioids for palliative care patients Availability of training in palliative care for social workers, psychologists, faith leaders and volunteers Funding and financial models used for palliative and end-of-life care services

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Type of Indicator	Indicator
Outcome	<ul style="list-style-type: none"> Overall survival and disease-free survival Functional status Rate of return to work among working-age survivors* Measurement of patient and family satisfaction, QOL and general well-being Proportion of cancer patients dying within and outside healthcare facilities

* EUROCHIP indicators: Available at: <http://www.tumori.net/eurochip/indicators.php?page=list>. (Accessed: November 2016).

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CHAPTER 5

RESEARCHING CANCER AND CANCER SURVEILLANCE

1.0 INTRODUCTION

1.1 Cancer Research

In the early 1970s just a quarter of people diagnosed with cancer were still alive ten years after their diagnosis. Nowadays, 50% of all people diagnosed with cancer can expect to survive their disease diagnosis for at least ten years. Survival rates for a number of cancers such as breast cancer, skin melanoma, testicular cancer and paediatric leukaemia have shown dramatic improvements in survival over the past 40 years. But many cancer patients still do not survive, and there remain groups for whom outcomes are particularly poor, including pancreatic, oesophageal and lung cancers, brain tumours, and many rarer cancers. In recent years the understanding of cancer has significantly improved, and together with impressive technological advances this has created exciting opportunities to develop new ways to prevent, diagnose and treat this complex set of diseases.

Cancer research is a complex global activity aimed at controlling a complicated disease. Continuous improvement in the quality of services being delivered to cancer patients depends on the accumulation of evidence from clinical and non-clinical research studies undertaken in several countries and centres around the world.

Research continues to be pivotal in the development of our understanding of and in the prevention, management and treatment of cancer. It is at the heart of the progress we have seen in the doubling of cancer survival over the last 40 years. It will therefore remain essential if we are to continue driving improvements forward. Efforts to control and cure cancer are multifaceted and subject to many interdependencies and diverse funding streams.

Organisational, financial, specialised human resources and infrastructural support (especially in the requisite ICT technology) are all required to develop and sustain a national research agenda. Additional resources and developments are required to strengthen each of the traditional research cultures; still often compartmentalized into two specific domains (non-clinical/ laboratory and clinical) and both domains need to be helped to interact more actively.

The over-arching objective of cancer research is to combat cancer by developing improved patient-oriented strategies, from prevention to more effective and earlier diagnosis and better treatment with minimal side effects. A significant trend in cancer research is therefore concentrating on translating the knowledge being created by genomics and other fields of basic research into applications that improve prevention, treatment, clinical practice and public health (European Association of Cancer Research, 2007). The involvement of public and private oriented healthcare and academic institutions and increasingly enterprise is highly encouraged in all topics in this particular and prominent field of research.

The patient-oriented approach to cancer research can include the following four inter-linked components:

1. Establishing facilities and developing initiatives for the exploitation of research on cancer in Malta and develop a national cancer research agenda.

2. Supporting clinical research, particularly participation in international collaborations and clinical trials, aimed at validating new and improved interventions.
3. Supporting translational research aimed at bringing basic knowledge through to applications in clinical practice and public health.
4. Promoting research in emerging or 'underserved' areas related to cancer care and control such as ageing and cancer; inequalities in cancer care and outcomes; health promotion and health communication for cancer control and care; improving the quality of life of cancer patients and survivors (including psycho-social aspects, palliative care and survivorship issues); health economics and cancer control strategies; rare cancers and guidance to support groups .⁷

1.2 Cancer registration and surveillance

Cancer surveillance and information is an important tool in helping to reduce the risk of cancer in the entire population and to improve outcomes for people diagnosed with cancer. Population-based cancer registries are essential in providing objective and standardised information on both risk factors and their impact on cancer incidence, as well as on patterns of care and outcomes of cancer patients. Linkage of several sources to a central register of cancer patients is essential if their value is to be maximised. For cancer risk, information primarily comes from official statistics and community surveys; for cancer services, several primary sources need to be tapped and linked and include data on hospital clinical and administrative activity and patient medical records. Collaborations with available bio-banks also need to be explored.

Registration of cancer at population level can identify trends in cancer that will enable researchers to generate hypotheses, pose and address questions about the findings and can help refine and further advance the overall scientific and cancer control services community understanding of how the cancer burden will evolve over time. Population-based cancer registries can also facilitate and support research and the planning and management of cancer services. Examples of how and why cancer registry information can be used by researchers can include: answering questions about cancer causation, prevention, treatment and control; locating geographic areas with higher than average rates of cancer; studying patterns and outcomes of cancer care; estimating the cost of cancer and identifying risk groups for research and intervention programmes. Access to a cancer registry can also facilitate case-control, cohort and randomised control research into cancer aetiology and outcomes (Martin-Moreno et al., 2015).

At the national level, the registry allows the tracking of progress and trends and thus identifying measures which are effective and those that are not. The registry also permits health system planners to know how many services are needed (both now and in the future) and in what areas. Additionally, the registry engaged in international networks allows the comparison of its outcomes with those of registries elsewhere. This is of particular usefulness for the national health system to establish and monitor progress towards aspirational benchmarks and for the international health community to facilitate the identification of potential risk or protective factors which may vary from country to country. Finally, cancer registries can be engaged to contribute to the international collation of 'big data' that can be used for activities such as for the development of algorithms that can be derived to infer patient outcomes and long term sequelae from these databases.

7. Adapted from Community Research and Development Information Service (2004) Combating cancer. Available at: https://cordis.europa.eu/pub/lifescihealth/docs/wp-combating-cancer2up_en.pdf. (Accessed: December 2016).

The Malta National Cancer Registry already performs all the above objectives. It already provides extensive information on cancer incidence, prevalence, survival, and mortality. The national registry also has the capacity to deliver trends and projections on each of these domains. However, there is an affirmed need to strengthen its source base and to further develop its functions and capabilities so that it can supply more detailed and timely information on domains that still need substantial development such as stage at diagnosis and the patients' journeys along their cancer care pathways including delivery and outcomes of clinical care and treatment. The ultimate aim is to amplify its ability to utilize the information it collects and analyses to advance medical knowledge on cancer at the national and international level. Furthermore, the cancer registry has a role in the quality assurance assessments of the cancer care services, and consequently in the promotion of standards of care and initiatives for continuous quality improvement. Standardised indicators for major/specific cancer sites recommended by international cancer networks and initiatives can be adopted.

The National Cancer Plan is aiming at establishing facilities and developing initiatives for the advancement and support of research on cancer in Malta, for the development of a national cancer research agenda and for the further development of cancer registration and surveillance in Malta. The Plan is putting forward the following measures:

1. Setting up of a national Cancer Research Foundation (CRF). The CRF will be an organisational structure which is setup through a formal agreement and comprises representation, resourcing and financial allocation from the Department of Health, clinical and academic sectors. The CRF will inter alia be responsible for leading and coordinating the following actions:

- a. **Map current research activity in terms of objectives and funding to better understand where further public support is needed, where increased coordination would be desirable, recommend and promote national priorities for research and seek sources for new, augmented and research-dedicated funding (including EU-funded initiatives). Due priority and prominence will be given to areas of research concerned with emerging or under-served areas related to cancer care and control. Examples of these areas have been included on page 88 (bullet 4).**
- b. **Set up a national cancer research register to keep track of all research activity (both present and past research). This repository will also allow the monitoring and dissemination of information on progress of ongoing research.**
- c. **Identify and manage sources of funding to avoid duplication and improve efficiency in the utilisation of available resources. Funding for the coordination of translational research in hospitals and basic research in the academic institutions needs to be better structured.**
- d. **Formation and support of a network and communication channels between different research groups in Malta including health care providers from different clinical disciplines to increase connectivity and collaboration between these groups.**
- e. **Promote public-private partnerships between policy makers, researchers and the industry. Support a network of cooperation among the academic institutions, hospitals and the various concerned industrial partners who engage in research activities so that the connection between basic and clinical research improves.**
- f. **Support training in basic and translational research for healthcare professionals and other researchers.**
- g. **Advocate for the provision of career progression pathways for professionals involved in research at both the academic and the clinical levels.**
- h. **Design, promote and support the dissemination of good practices that advance transparent and ethical collaboration for research.**

2. Creation of a regulatory framework for cancer research. This will require the revision of any existing and/or the creation and enactment of new legal provisions that on the one hand enable and facilitate the conduction of cancer research and on the other respects and protects the rights and obligations of patients involved in research and clinical trials and also the rights and obligations of the clinicians and researchers participating in these research initiatives. The regulatory framework will seek to:

- a. enforce data protection controls in ways that are reasonable, appropriate, enabling of research and follow and uphold the relevant ethical principles.
- b. seek to give opportunities for involved parties (including patients' groups) to present their constructive views on what is appropriate and feasible.

3. Securing investment for cancer research and cancer registration and surveillance. Investment is required to enable and support cancer research includes:

- a. ring-fenced working time for the conduction of research for clinicians, scientists and other participating professionals;
- b. provision of career progression pathways for professionals involved in research at both the academic and the clinical levels;
- c. funding streams to allow networking (including travel) with international research collaborations and institutions;
- d. ICT systems infrastructure and support;
- e. procurement and updating of equipment and facilities needed for research work;
- f. provision of under-graduate and post-graduate opportunities and exposure to training in research methodologies and practice. Under-graduate and post-graduate educational programmes need to place greater emphasis to the value of research and research methodologies and practices.

4. Consolidate and support the functioning of the Cancer Registry through:

- a. increasing the skilled human resources engaged in the Directorate of Health Information and Research and in particular the Cancer Registry.
- b. addressing existing legal, human resources and technological barriers to the collection of data for cancer registration, through:
 - strengthening the legal basis for the functioning of the cancer registry. The legal framework is necessary to mandate collection of cancer information for registry purposes, ensure uninterrupted and secure data sharing and linkage and with several sources and regulate the terms of data ownership and control.
 - increasing the skilled human resources engaged in the Directorate of Health Information and Research and in particular the Cancer Registry. The capability of the cancer registry to participate in international cancer registration collaboration needs to be ensured, promoted and safeguarded.
 - increasing the inter-operability and capability of extracting data through stable electronic linkage of the registry with its multiple sources of information and especially with the databases for histo- and cyto-pathology and cancer screening, clinical patients' records at the Oncology Centre and specialised clinics such as the Breast Clinic and facilitated access to electronic medical records.
 - investing and managing in a comprehensive and integrated clinical information management system that can follow the cancer patients throughout their cancer journey.
- c. extending the scope and range of data available to the Cancer Registry in order to allow the Registry to better contribute towards a more comprehensive cancer surveillance and monitor clinical activity and outcomes. Cancer Surveillance needs to expand to:

- monitor more closely and in a timelier fashion trends in cancer incidence, prevalence and survival over time and between different geographical areas, social groups, and other defined populations;
- evaluate the effectiveness of cancer prevention and screening;
- evaluate the quality and outcomes of cancer care;
- evaluate the impact of environmental and social factors on cancer risk;
- support investigations into the causes of cancer;
- provide information in support of cancer genetic counselling services for individuals and families at higher risk of developing cancer.

5. Empowering patient participation in cancer research. Increased patient participation in cancer research requires the amplification of:

- a. knowledge dissemination to patients so that they are enabled to better understand the research processes and give a regularly updated and informed consent.
- b. involvement of patients and their caregivers in the setting of the research agenda to ensure that policy priorities are in line with patients' priorities.
- c. interaction with patients in particular research fields (such as quality of life, palliative care, survivorship, psycho-oncology or rare diseases) in which patient experiences and patients reported outcomes have the highest potential to enrich findings.

2.0 Conclusion

Investment in cancer research and cancer surveillance will only attain its objectives if it can be converted into interventions that benefit patients. Multidisciplinary collaboration and close proximity between the laboratory for basic scientific research and research in the clinic is at the core of effective translation. A number of traditional barriers between basic and clinical research need to be removed or minimised and facilitation of an iterative approach between the two domains needs to be stepped up.

In Malta, there is as yet a substantial and untapped potential for cancer research at both the national and international level. In this context, there is the need to invest and build a stronger and more creative foundation for research in general and cancer research in particular with the establishment of a coordination and unifying structure and a stronger but enabling regulatory framework so that this potential is unleashed, encouraged and nurtured to achieve the anticipated growth over the next few years.

3.0 INDICATORS

Type of Indicator	Indicator
Structure	<ul style="list-style-type: none"> Per capita expenditure on cancer research Number of researchers (in the clinical and non-clinical domains) Sources of public financing of cancer research (budgets from Ministry of Health, University of Malta, other Ministries, industry, EU funding, other entities) Share of total expenditure on cancer research on the total research expenditure at the national level Percentage of target population covered by cancer registries Adequacy of human, financial and technical resources to support core registry activities, including data collection, quality assurance and dissemination Number of core registration items collected by the registry (compared to the full list of core items for European registries, as agreed by the European Network of Cancer Registries - ENCR). Available from: http://www.enrc.eu/images/docs/recommendations/recommendations.pdf
Process	<ul style="list-style-type: none"> Number of new and ongoing research projects (clinical and translational) Evidence of involvement of patients in clinical research Timeliness of ascertainment and reporting Regular quality assurance to ensure quality and international comparability of data (in line with International Agency for Research on Cancer - IARC and ENCR guidelines) Acceptance of the data by IARC for "Cancer Incidence in Five Continents" and for EUROCARE studies on cancer survival Completeness of ascertainment of cases, as assessed by quantitative methods
Outcome	<ul style="list-style-type: none"> Evidence of improved research outcomes in the field of cancer Clinical data available (stage, treatment, diagnostic procedures) Completeness of follow-up of all cases to date of death Compliance with all legal and administrative obligations with regard to data confidentiality and security

Indicators adapted from: Martin-Moreno, J.M., Jelenc, M., Gorgojo, L. and Harris, M. (2015) European guide for quality national cancer control programmes. Ljubljana, Slovenia: National Institute of Public Health.

Note: The topmost indicators in each row are designed to monitor developments in Cancer Research while the following group (separated by a space) are included to monitor Cancer Registration and Surveillance.

References:

Community Research and Development Information Service (2004) *Combating cancer*. Available at: https://cordis.europa.eu/pub/lifescihealth/docs/wp-combating-cancer2up_en.pdf. (Accessed: December 2016).

European Association for Cancer Research (2007) Available at: <http://www.eacr.org/about-us>. (Accessed: December 2016).

Martin-Moreno, J.M., Jelenc, M., Gorgojo, L. and Harris, M. (2015) *European guide for quality national cancer control programmes*. Ljubljana, Slovenia: National Institute of Public Health.

CHAPTER 6

GOVERNANCE AND RESOURCES FOR CANCER CONTROL

1.0 INTRODUCTION

1.1 Governance

One of the most complex disease management segments of healthcare is the management and development of cancer control services. The broad scope and the involvement of a great number of actors in the governance of cancer necessitates well planned, resourced and supported structures for the planning, management and monitoring of all resources needed in healthcare for cancer management (Martin-Moreno, 2015).

To effectively discharge its stewardship function, the Ministry responsible for Health needs to gather and use intelligence to formulate overall health policy, establish policy direction, and create an appropriate regulatory and project management environment to implement these policies.

Health system governance and macro-organisation refers to the way the Ministry of Health (or the relevant national agency) manages the health system, as well as the structural arrangements for purchasers, providers and market regulators (Atun et al., 2005). Macro-organisational structure needs to:

- include appropriate and structured engagement of the responsible authorities,
- ensure explicit accountability for delivering and implementing the plan, and
- be backed up by a well-resourced and robust registry and comprehensive surveillance framework for ongoing monitoring and evaluation functions and activity.

The growing importance given to issues of governance is driven by the need for greater accountability. This interest is arising from both the increasing funding of health and health care systems as well as the growing demand by stakeholders to demonstrate results (NHSS, 2014). This acquires special resonance for the governance and implementation of the National Cancer Plan, since controlling cancer requires the investment of substantial resources and the effective coordination of an extensive array of stakeholders and participants.

1.2 Resources for Cancer Control

The development of the right institutional and professional capacity is a challenge which takes time, strategic planning and needs to be forward-looking. A comprehensive approach is required for the planning and acquisition of organisational, human, technological and financial resources. Planning also needs to be supplemented with regular and systematic analysis of changes in the demand for and supply of cancer control services in order to ensure the continued delivery of high quality services. If challenges such as shortages and inadequate access become evident, timely and flexible policy actions that can foresee and resolve emerging problems need to be in place (Martin-Moreno, 2015).

Health care in general and cancer care in particular can be very expensive (Meropol and Schulman, 2007). Moreover, costs are rising at a rate that outpaces inflation and consumes an increasing share of expenditures at all budgetary levels, from national to individual, in almost all countries (Sullivan et al., 2011).

The implementation of the National Cancer Plan (NCP) is dependent on the availability of the required resources for the prevention and coordinated treatment of cancer and for monitoring and research aimed at controlling cancer wherever possible. The necessary assets to support a national cancer plan need to be defined, financially-supported and guaranteed in line with the overall national health systems policy (Martin-Moreno, 2015). The resource requirements and related issues discussed below in this chapter should be considered in close liaison with the issues discussed in the chapter on governance.

A. Human resources

Although increasing drug expenditures are a matter of active debate among stakeholders and providers of cancer care, costs associated with staff utilization are often neglected and there is a scarcity of evidence that demonstrates or models the relationship between patient workload and human resource needs. Published reviews have estimated that costs other than those for cancer drugs, such as administration procedures, evaluation and management, and laboratory and radiology services can account to about 30% of total spending for cancer care (Fasola et al., 2012).

There is a multitude of healthcare professionals and other workers (including management, quality assurance and ICT professionals and administrative support staff) that are involved in the provision of cancer control services. Numerous professionals are employed in health promotion and disease prevention services, in organised cancer screening services and also in primary and community healthcare services. Primary healthcare professionals and general practitioners in particular have a key and increasing role in identifying the early symptoms and signs of cancer, and the role of patient navigator which can be selected from various professional groups is gaining increased recognition.

However, the most heightened intensity of specialised healthcare workforce for cancer care can be found in the secondary care sector. These professionals are found both in the general hospital setting with regards to professionals dealing with the pathological and radiological identification of neoplasms and the surgical or radiological interventions to remove or contain them and also in the specialised oncology centre setting with regards to oncological treatments that can take the form of radiotherapy or chemotherapy and in palliative and end-of-life care. Furthermore, several professionals (including professionals from the social care sector) are involved in rehabilitation care and survivors' support services. These workers can be based in several of the above-mentioned settings as well as in specialised rehabilitation facilities and in the community.

Human resources are one of the three principle health system inputs, with the other two major inputs being physical capital and consumables (see Figure 11). Arguably, human resources are actually the most important of the health system inputs since the performance and the benefits the system can deliver depend largely upon the knowledge, skills and motivation of those individuals responsible for delivering health services (World Health Organisation, 2000). The relationship between human resources and healthcare is very complex and effective Human Resources Management (HRM) strategies are greatly needed to achieve better outcomes from and access to health care (Kabene et al., 2006). Functional HRM practices are needed in order to find the appropriate balance of workforce supply and the ability of those practitioners to practice effectively and efficiently. A practitioner without adequate tools is as inefficient as having the tools without the practitioner.

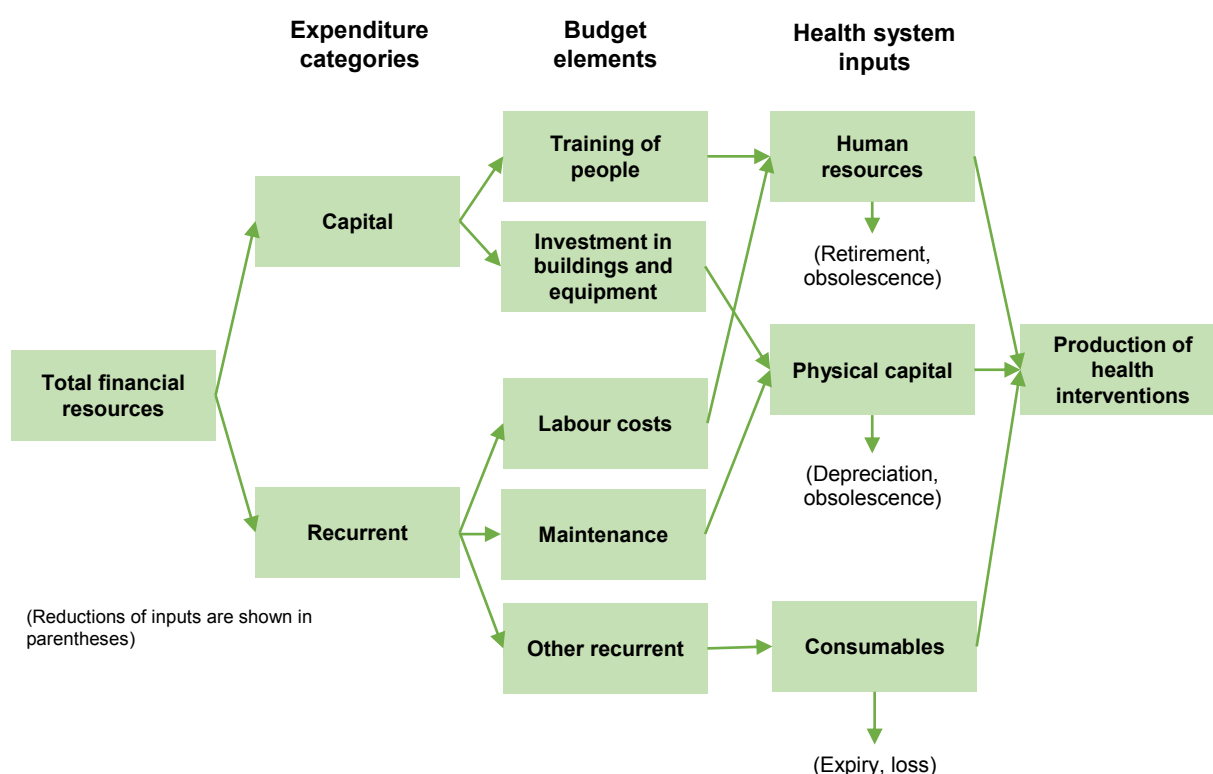


Figure 11: Relationship between health system inputs (human resources, physical capital and consumables), budget elements and expenditure categories. Source: World Health report 2000, Figure 4.1, pg. 75. Accessible from: <http://www.who.int/whr/2000/en/>. The financial resources to purchase these inputs are of both a capital investment and a recurrent character. As in other industries, investment decisions in health are critical because they are generally irreversible: they commit large amounts of money to places and activities that are difficult, even impossible, to cancel, close or scale down.

A1. Effective number and distribution of healthcare workforce and professionals

The magnitude, distribution and skill mix of the health workforce involved in the planning, delivery and monitoring of cancer control services are key measures of a country's capacity to deliver the intended services and interventions. These measures need to revolve around the important work of drawing up and regular updating of a Strategic HR Plan for cancer control services. Strategic HR planning is essential to ensure the achievement of the objectives and the ongoing development of the national cancer control policy and services (National Health Systems Strategy for Malta - NHSS, 2014: Strategic Direction 2A – making best use of available resources and ensuring sustained progress).

This Plan is promoting the development of a more strategic base for the HRM in cancer control. The work involved in the strategic HR planning process includes:

1. **Assessing available HR capacity including available complements and inventory of skills, qualifications, specialisations and current collective or individual development plans.**
2. **Forecasting HR requirements taking into consideration:**
 - **actions and targets delineated in the National Cancer Plan (refer to the four vertical chapters and their respective action plans);**
 - **current and projected increases in the cancer burden according to demographic and epidemiological trends and indicators;**

- health workforce characteristics (demographics including age and gender mix, sector/specialty, workload requirements, output/ efficiency) (Martin-Moreno, 2015).

3. Perform a gap analysis to determine the disparity between where the cancer control services want to be in the future and where they are now. The gap analysis includes identifying the number of staff and the skills and abilities required in the future in comparison to the current situation.

A2. Training, education and certification

Securing high quality cancer care necessitates that the provision of several training, education, support and certification services and processes are in place to ensure that professionals are well-prepared and their support needs are catered for.

This Plan is promoting the following provision considerations for the domain of training, education and certification:

- Specialist training programmes for high-priority medical specialties and leading to speciality registration;
- Increased, diversified, regular, sustained and frequent opportunities for continuing professional development and education programmes related to oncological care, for both primary care and specialist physicians, nurses, allied healthcare professionals and medical support staff;
- Inclusion of integrated care principles within curricula for the training of healthcare professionals (both at under-graduate and post-graduate levels);
- Specific requirements for modules on patient communication and other necessary soft skills such as listening, patient handling and inter-personal skills for all professionals and staff working with cancer patients;
- Support services including psychological support (pre-emptive and reactionary) and incentives to attract, recruit and retain the necessary complement of workforce members.

B. Healthcare settings, ICT infrastructure and connectivity

Cancer-related health services in Malta are offered in a variety of health facilities. However, most activity concerning diagnosis and treatment takes place at the Sir Anthony Mamo Oncology Centre, Mater Dei Hospital and to a lesser extent the acute general hospital in Gozo. Issues concerning access to cancer care services offered in these medical facilities are dominated by issues involving waiting times for first and subsequent appointments for out-patients and start of treatment.

These challenges require a special, sustained and focussed effort and investment in the appropriate instruments and personnel in order to allow more granular and real-time knowledge of the status on an individual patients' basis. This is placing the development and implementation of a comprehensive ICT system that records every important step in a patient's cancer care pathway as an inescapable delivery of the NCP. A patient's record must include relevant information that bridges her/ his movements from one module to another beginning from the referral started in the primary care setting, through her/ his journey for diagnosis and definitive treatment and continuing after the completion of the acute treatment stages into rehabilitation, follow-up, survivorship and palliative phases.

A number of these modules are already operating (e.g. the system at the National Screening Unit). However, several new modules still require extensive design and implementation. These include modules required for a number of clinics at Mater Dei Hospital and the major undertaking that needs to be developed for the whole of the Oncology Centre.

Investment in the appropriate equipment and associated software necessitates that it is complemented with the recruitment and training of personnel that will be tasked with the operations, analysis and interpretation and support of these systems. The deployment or recruitment of appropriately trained personnel is crucial for this essential activity.

Apart from the monitoring of patients' timelines and journeys, this infrastructure is an inevitable pre-requisite for the promotion of the cancer care services in Malta for the purposes of research (clinical and non-clinical), networking between national settings and with centres of reference abroad and also for the evaluation of outcomes and quality assurance of the standards of care.

C. Health Technology

Healthcare economists estimate that 40–50% of annual increases in healthcare expenditure can be traced to new technologies or the intensified use of older ones (Callahan, 2008). Health technology is a major driver of increasing costs in cancer services, challenging the delicate cost-effectiveness equilibrium (Martin-Moreno, 2015).

Health technology is an umbrella term that can be used to cover both equipment and cancer therapy that mainly involves the use of cancer drugs. The general recommendation is to continue upgrading the available technology in all the major aspects of cancer care (screening, diagnosis and treatment) in a planned and incremental manner and to use cancer control drugs in a more stratified manner in order to ensure a higher yield of successful use and outcomes. These two different sub-groups will be further examined separately in the following text.

C1. Equipment

There is a vast array of increasingly sophisticated and expensive equipment that is directly involved in the diagnosis and treatment of cancer. The operation of new and additional equipment as well as the upgrading of existing functional machines is heavily dependent on the availability of adequate complement of trained professionals. Therefore, plans in this area of development are inseparable from strategic plans for human resource recruitment and development. Core classes of technological equipment for cancer control include:

C1.1: Mammography equipment – used both for the breast screening service as well as in the imaging facilities for women presenting with symptomatic disease and for follow-up of cancer patients after the completion of active treatment.

C1.2: Equipment used in cancer surgery – the goals for surgery vary and conventional surgical techniques can be used for inter alia diagnostic, staging, tumour removal as in curative or primary surgery, de-bulking, palliation, reconstruction and prevention as in the removal of precancerous lesions and prophylactic removal of organs such as breast and ovaries in high risk individuals. Furthermore, the Plan is advocating for the planned and incremental increase in the capacity for established and emerging techniques and corresponding availability of new equipment for more minimally invasive, laparoscopic, endoscopic, laser assisted and oncoplastic surgery. These new methods can accrue benefits both for the patients (for example from less invasive interventions and immediate reconstruction procedures) as well as for the healthcare system from reduced hospital stays and repeated admissions with the resultant increased capacity to deal with an increasing demand.

C1.3: Equipment based at the Imaging Department – different kinds of imaging/ radiological techniques can be used to diagnose and treat cancer. Major diagnostic equipment for ultrasound examinations, computerized tomography (CT scanners), nuclear magnetic resonance (MRIs) and positron emission tomography (PET

scanners) are now all available in the public national healthcare services. This Plan is recommending the planned and incremental increase in the supply and updating of these diagnostic equipment (including equipment and radioisotope supplies for nuclear medicine) to cater for the forecasted increase in demand and the inclusion of new capabilities that can be performed with more up-to-date models and acquired expertise. Additionally, it is placing a special focus on interventional radiology in particular in the field of tumour ablation methods such as for the removal of localized but difficult to resect tumours.

C1.4: Laboratory capacity to support screening, diagnosis and treatment needs – nearly all cancer diagnosis are based on microscopic evidence showing the presence of malignant cells and tissues. Furthermore, nearly all the branches of conventional pathology are involved in cancer screening, diagnosis and progression of treatment apart from the major impact of the haematology, histological and cytological departments on cancer diagnosis and follow-up. Specialised branches of biochemistry and virology are essential in the screening for colorectal and cervical cancers respectively, while other sectors such general pathology, immunology and micro-biology are vital for the assessment of patients prior, during and after the completion of treatments for cancer. A structure for the planned and incremental increase and updating of the available equipment and expertise in pathology techniques is incorporated in this Plan to address the expected increase in demand and realise the introduction of evidence-based and cost-effective new procedures.

C1.5: Increase national capability in molecular diagnostics and genomics - there is a constantly increasing scientific understanding that cancers which arise in the same part of the body and appear the same by conventional pathology may have highly heterogeneous prognoses, determined by specific molecular changes in the individual patient's cells. Special focus is being stimulated for the evaluation of the scope of these evolving sectors as they are becoming increasingly critical for optimizing prevention and effective treatment through for example the adoption of stratified approaches for the active surveillance of individuals at high risk and molecular testing to guide the cancer treatment of more hematological and solid tumours.

C1.6: Radiotherapy equipment - with the transfer of the oncology services to the Sir Anthony Mamo Oncology Centre, radiotherapy in Malta has undergone a major leap in the portfolio of treatments available and the accuracy of treatment planning and administration. These new machines use sophisticated imaging direction techniques for the delivery of more focused beams resulting in the decrease in the incidence of complications and side-effects from radiating adjacent healthy tissues. Benefits are accrued by both the patients and the service from the shortening of each therapy session and of the total duration of the treatment schedule. The Plan will oversee the introduction of additional new radiotherapy target accuracy levels and treatment modalities to achieve higher conformal dose distributions with improved target volume coverage and sparing of normal tissues compared with conventional radiotherapy and brachytherapy (also sometimes called 'internal radiation') procedures which involve the insertion of radioactive implants inside the tissues that need targeted radiation treatment.

C2. Cancer drug therapy (Chemotherapy and other systematic treatment)

Drugs for cancer treatment and their rapid uptake are important for providing modern and advanced treatment options for cancer patients. Chemotherapy and other systemic therapies are playing an ever-increasing vital role in the treatment of cancer. These medicines can be used as the primary form of treatment or as a supplement or in combination with other treatments. They can be used with the intent to cure cancer, decelerate the progression of disease (e.g. with hormone therapy) and to offer palliation to help ease the symptoms of cancer and improve quality of life.

Systematic treatment is a major cost driver of cancer care and the availability of the number of novel systematic interventions (several of which can be progressively classified as molecularly targeted agents⁸) has shown a marked and amplified cost trajectory over the past decade. Patients are understandably keen to have access to the full range of treatment options becoming available and consequently healthcare providers are being faced with recurrent dilemmas of approving or withholding access to exceedingly expensive drug treatments on an individual patient basis. Considerations take into account inter alia costs and expected benefit (in terms of impact on survival and quality of life) at the societal/ community and individuals' level. Furthermore, few treatments can actually be demonstrated to show clear and major wins with the majority falling into the categories of substantial costs for limited or marginal benefit (Sullivan et al., 2011).

The Plan is advocating actions that aim towards improving the agility of the structures and processes by which cancer drugs that are shown to be effective for specific indications are approved for addition to the national formulary and are made available to the patients for whom they are prescribed. These strategies are basically geared towards the central objective of investing according to the demonstrated effectiveness of the cancer drugs treatments.

- 1. Strengthening the institutional and professional capacity for Health Technology Assessments (HTAs) for medicines. The necessary structure and mechanisms are already in place and active within the Directorate for Pharmaceutical Affairs. However, constant updating and plans for upgrading the human resources and expertise to increase the robustness and agility by which HTAs are conducted is required particularly in view of the forecasted increase in demand. Malta's continued participation in EUnetHTA⁹ will be supported. Additionally, in the light of the heightened advances in genomics and personalised medicine, it is especially important to enhance the national capability to enable faster 'pairing' of innovative and experimental drugs with patients who could potentially benefit from them. Due to the sensitivities concerning the uptake of new cancer drugs, it is very important to demonstrate that these mechanisms are as independent and transparent as much as possible, take into consideration issues of efficacy, efficiency, equity and quality and should also involve patient and public representation (Martin-Moreno, 2015).**
- 2. Develop parallel structured processes to, where possible, allow disinvestment of cancer care that is shown to be inadequately cost-effective and/ or poorly effective compared to other options.**
- 3. Delays in assessing the value for money of new treatments and in statutory approval processes once safety and effectiveness have been established can be harmful and costly (OECD, 2013). Strengthening the cross-national harmonisation and mutual recognition of the approval processes to reduce regulatory delays will be pursued by reinforcing our national connectivity and collaboration activities with the relevant EU institutions. Furthermore, the Plan is advocating that Malta contributes towards the evaluation of new and emerging mechanisms for cooperation at EU-level such as the sharing of resources (including reference networks) and joint procurement of drugs and medical devices.**

8. Molecularly targeted agents are drugs or other substances that block the growth or spread of cancer by interfering with specific molecules ("molecular targets") that are involved in the growth, progression and spread of cancer. They are also referred to as "molecularly targeted drugs or therapies" and "precision medicines" or similar names. There are several classes include hormone therapies and immune-therapies. Biological agents such cancer vaccines and gene therapy are often also included within this heading. National Cancer Institute (2014). Available from: <http://www.cancer.gov/about-cancer/treatment/types/targeted-therapies/targeted-therapies-fact-sheet>

9. EUnetHTA: European network for Health Technology Assessment. Accessible from: <http://www.eunetha.eu/>

4. Enhancing the delivery of evidence-based and current best practice, and reducing unacceptable variations in care standards and processes. The development of national clinical guidelines and protocols for the management of the most common cancers will be prioritised over the duration of this Plan. This will involve the setting up of appropriately resourced, supported and multi-disciplinary Tumour Management Boards (TMBs). These TMBs can develop as an extension of the respective Multi-Disciplinary Teams (MDTs) and the guidelines issued by these Boards will become a pre-requisite and an integral part of the assessment and approval systems for new cancer drugs. Another important development will be securing a clinical pharmacist service in the oncology and haematology sectors. Clinical pharmacists apply specialized knowledge of the scientific and clinical use of medications, including medication action, dosing, adverse effects, and drug interactions and complement all the initiatives being taken to address appropriate and safe drug therapy provision. These specialists are also key contributors to protocol formation, patient appraisal and assessments and drug reviews.

5. Allocating and securing adequate financial resources to allow the procurement of and affordable access to new and effective drugs. The Plan is promoting the establishment of a ring-fenced annual budget that will help accelerate the introduction of the new cancer drugs. The Exceptional Medicinal Treatment Policy (EMTP) route will be reinstituted in line with its original objectives, namely that of being a truly exceptional route to be followed in unique circumstances such as very rare or childhood cancers. The inclusion of new processes such as fast-track HTA procedures and closer monitoring of agreed indicators that show efficacy of treatment will effectively minimize as much as possible the drugs requested via this path.

6. Strengthening the monitoring of the use, delivery and timeliness of cancer drugs and the outcomes of patients receiving these therapies. Achieving the latter requires the availability of robust processes that can measure and investigate the quality of life of patients receiving treatment and other issues related to the quality of care and patient safety such complications, side-effects and adverse events. This strategy is highly dependent on the development and implementation of the comprehensive ICT system that records every important step in a patient's cancer care pathway mentioned in section B. above, the establishment of a functional reporting for clinical risk management and the strengthening by investing more in the National Cancer Registry. Cancer registries are essential for international and national benchmarking and the provision of internationally comparable cancer survival estimates by cancer stage data since the success of cancer treatment is critically dependent upon the stage of disease at which treatment is initiated.

7. Engage in and support research at the different levels (e.g. scientific, pharmaceutical, clinical, epidemiological). The Plan is promoting an amplification in the collaboration and synergies between the Department of Health, the healthcare providers, the research community in Malta (mainly at the University of Malta) and the pharmaceutical industry in order to identify research priorities in this area and to be able to better use the national resources available in the different organisational setups for cancer research purposes. Increasing the accessibility of Maltese patients for inclusion in clinical trials is another important objective of this Plan in this area.

D. Cancer-specific Expenditure

The ability to deliver affordable cancer care is at a crossroads. A volatile mixture of demographics (ageing and expanding populations), rapid developments of new technologies (such as medicines and surgery), and increasing healthcare expenditure is driving cancer costs upwards (Sullivan et al., 2011). Given the finite nature of resources, every expenditure and investment decision means that other treatments must be given up, whether in cancer care

or in other fields of health care. An OECD publication (2013) comparing cancer care between countries reported that cancer costs amounted to around 5-6% of the annual total healthcare expenditure of OECD members.

Expenditures for cancer control are extremely complex to compute. Frequently, they are incurred by facilities or structures that are not committed only to cancer control activity and services (such as disease prevention, palliative care, rehabilitation care, surgical units). However, there are several streams of expenditure that are very cancer specific and these include cancer screening programmes, oncological cancer treatment (medicines and radiotherapy), population-based cancer registries and cancer-related information systems and costs associated with the management, implementation and evaluation of the NCP itself. In addition, as already amplified in a number of earlier sections in this chapter, the ongoing and rapid advances in cancer control require access to financing mechanisms that are adequately flexible and agile to be able to cater for the associated inflationary expenditure.

The Plan includes the following actions aimed at generating more intelligence on national cancer control and associated expenditure, rationalising and re-directing expenditure towards more cost-effective outcomes and the identification of alternative funding streams to supplement the financing of the national health system,

1. **Collecting more granular financial health information from the public health system in order to provide better estimates for planning and budgetary calculations (NHSS, 2014: 93). This is presently only available at aggregate level and further micro-analysis of health expenditure by disease groups is in effect hampered by the shortage of the necessary sources and granular data. Better prioritisation of future investments and more efficiency in the use of health care service funds thus releasing some funds to allow the continuity of other important services will be greatly facilitated with the availability of the appropriate financial intelligence by disease-specific groups and in the case of cancer by major cancer diagnostic groups. The potential of collecting OECD System of Health Accounts (SHA) according to an agreed shortlist based on ICD that was endorsed by the European Commission's EUROCHIP-III Common Action (the European Cancer Health Indicator Project) (Baili, Amati and Micheli, 2012) will be explored with a view of adapting and adopting these indicators to our specific national context.**
2. **Re-engineering services to achieve lower costs in safe settings (Martin-Moreno, 2015). Examples can include:**
 - a. **where possible, move cancer care out of hospital to primary and community care settings;**
 - b. **optimise use of oral and other cancer medicines that allow patients to be treated safely at home or in other community settings;**
 - c. **invest in methodologies that can accurately help in the stratification of patients to optimise the effectiveness of targeted cancer medicines;**
 - d. **continue, augment and seek to increase the efficiency of practices to procure high-quality off-patent medicines.**
3. **Studying the suitability of new or alternative revenue streams that can be used to supplement the financing of the national health system (NHSS, 2014: 93). In several developed countries, the national health expenditure has been shown to grow faster than the rest of the economy (OECD, 2011). This is driven by not only an ageing population, but also due to ever higher prices of effective drugs in a variety of diseases, with a major focus on oncology drugs and orphan drugs intended for use in rare diseases. The advent of molecularly targeted agents has changed the therapeutic scenario in oncology. These new drugs are delivering better results but, unfortunately at a much higher cost per item and hence per patient. The exorbitant price for these medicines is in part generated by the high costs of the research that goes into the development of these drugs. On the other hand, these new drugs are shown to in most cases either lifesaving or else provide a material extension to life expectancy (NICE – UK, 2013).**

The overall governance of this National Cancer Plan will be the responsibility of the Chief Medical Officer and the different units within the Department of Policy in Health including the Policy Development Unit, the implementation surveillance and evaluation setup which will be created and resourced for this specific purposes, the Department of Health Information and Research and the National Cancer Registry.

2.0 Conclusion

Governance in health does not only imply the management of resources within health care. It also needs to incorporate collaboration with other departments and agencies in government as well as with other sectors that include the private sector, voluntary organisations, social partners and civil society.

The broad scope and the multiple elements involving a great number of actors in the governance for cancer merits a strong structure in order to ensure that there is adequate:

- Management and planning of all resources required
- Secure adequate level of knowledge about cancer for the population
- Coordinate, manage and ensure stability of the requisite organizational support and financing for the promulgation of comprehensive cancer services, including: screening, diagnosis, treatment and rehabilitation, and services supporting cancer patients beyond treatment and immediate oncological care.

The provision of affordable cancer control services necessitates the allocation of adequate, effective and sustainable resources to ensure fair and accessible cancer care to the members of the public and the patients that require these services. Resource allocation policies need to be forward looking and responsive to the current and emerging challenges (OECD, 2013). Furthermore, comprehensive data sources that allow systematic measurements, monitoring and reporting related to outcomes, costs, practice and quality of cancer care are essential to support better evaluation and promote improvement of cancer care performance. Different data sources such as administrative, clinical and survey data should be utilised for assessing cancer control systems and linking data would enable the provision of further insights.

3.0 Indicators

In general, most of the indicators that help monitor roll-out and implementation of plans for cancer resources fall into the “structural” category. Indicators are grouped according to the major categories detailed above.

The functions of governance and macro-organisation of the National Cancer Plan are informed by the monitoring of all indicators included in the other chapters of this Plan. The indicators included below and specifically demarcated for governance will supplement the other indicators as top-level policymaker controls.

3.0 INDICATORS

Category	Indicator
Governance	<ol style="list-style-type: none"> Structure: <ul style="list-style-type: none"> Adoption of the National Cancer Plan 2017-2021 Resourcing of the Dept. of Policy in Health for the governance, implementation and evaluation of the National Cancer Plan Process: <ul style="list-style-type: none"> Allocation of ear-marked funds for the implementation and sustainability of the measures included in this National Cancer Plan Monitoring the appropriateness of allocation, disbursement and use of the resources apportioned for the individual measures of the National Cancer Plan Outcome: <ul style="list-style-type: none"> Measurement and evaluation of the outcomes of the newly introduced, expanded and updated services and actions according to this National Cancer Plan
A. Human resources	<p>Existence of a written, needs-based Strategic HR Plan for building and maintaining human resource capacity in cancer control, according to priorities delineated in NCP. Considerations include:</p> <ul style="list-style-type: none"> Needs-based assessment based on epidemiologic and demographic indicators, and current workforce characteristics (age, sector/specialty, workload and productivity) Undergraduate, graduate, and continuing training; licensing and certification Worker retention, especially for high-priority disciplines, disciplines where shortages exist or with evident sustainability issues, and for underserved areas Administrative and supportive functions Ethical recruitment standards and practice
B. Healthcare settings and ICT infrastructure and connectivity	<ol style="list-style-type: none"> Per 100,000 population: <ul style="list-style-type: none"> Capacity for comprehensive cancer treatment capacity Cancer surgery facilities Hospital beds for oncology and palliative care Timelines and benchmarks across cancer care pathways Existence of a comprehensive ICT system that can cover and track patients along their whole cancer care pathway.
C1. Health technology: Equipment	<p>Per 100,000 population:</p> <ul style="list-style-type: none"> Radiotherapy units Mammography units 'Nuclear Magnetic Resonance' units Computer tomography (CT) scanner units Positron emission tomography (PET) units Immunological and molecular analysis facilities Number of laboratory units to support screening, diagnosis and treatment needs

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Category	Indicator
C2. Health technology: Cancer drug therapy	<ol style="list-style-type: none"> 1. Existence of clear ground rules and transparent criteria for decision-making related to approval for new cancer drugs 2. Average time for uptake of new cancer drugs in national formulary following approval by the European Medicines Agency (EMA) 3. Existence of a specific strategy to foster health technology and translational cancer research, including an explicit list of research priorities and provisions to increase recruitment of patients to clinical trials
D. Cancer-specific expenditure	<p>Budget lines for cancer expenditure in the following areas:</p> <ul style="list-style-type: none"> ▪ NCP governance, coordination and management ▪ Cancer registries and cancer-related information systems, including investments in technology ▪ Secondary prevention ▪ Primary and non-oncological specialised care, including nursing and allied healthcare professional services ▪ Cancer research ▪ Oncological care, including psycho-oncology ▪ Palliative care ▪ Long-term rehabilitation care ▪ Social support services ▪ Cancer innovation (a flexible line item to expedite uptake of life-saving cancer therapies)

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