

The National Health System Cancer Strategy

The National Health System Cancer Strategy

**Ministry of Health and Consumer Affairs
2006**

The National Health System Cancer Strategy

TECHNICAL DRAFTING COMMITTEE

Scientific Coordinator:

Eduardo Díaz-Rubio

Experts:

Nieves Ascunce Elizaga
Josep M. Borrás Andrés
Carmen Cabezas Peña
José Expósito Hernández
Vicente Guillem Porta
Blanca López-Ibor
Antonio Pascual López
Lorenzo Pascual López
Dulce Ramírez Puerta
Miguel Ángel Ripoll Lozano
Eugenio Santos de Dios

Ministry of Health and Consumer Affairs:

Alberto Infante Campos
Pilar Polo Sanz
Enrique Terol García
Paloma Soria Valle
Rosa Blanca Pérez López
María Santos Ichaso Hernández-Rubio
Ángel Abad Bassols

AUTONOMOUS COMMUNITY INSTITUTIONAL COMMITTEE

Andalusia: José Expósito Hernández
Aragon: Alejandro Tres Sánchez
Asturias (Principality of): Isabel Palacio Vázquez
Balearic Islands: Francisca González Porcel
Basque Country: María Luisa Artegoitia González
Canary Islands: Isabel Díez de Lastra Bosch
Cantabria: José Manuel López Vega
Castile-La Mancha: Javier Gil Madre
Castile and Leon: María Luisa Cuadrado
Catalonia: Reger Pla Farnós
Community of Valencia: Carlos Ferrer Albiach
Extremadura: Eulalio Ruiz Muñoz
Galicia: Rafael López López
Madrid (Community of): Andrés González Navarro
Murcia (Region of): Agustín Navarrate Montoya
Navarra (Foral Community): Nieves Ascunce Elizaga
Rioja: Adolfo Cestafe Martínez
Ingsa (Ceuta-Melilla): Agustín Cotano Méndez

METHODOLOGICAL SUPPORT

Juan Carlos Abanades Herraz

Published and distributed by:

© MINISTERIO DE SANIDAD Y CONSUMO
CENTRO DE PUBLICACIONES
Paseo del Prado, 18. 28014 Madrid

Official Publication Identification Number (NIPO):

The copyright and other intellectual property rights of this document pertain to the Ministry of Health and Consumer Affairs. Healthcare organizations are authorized to copy this document, in full or in part, for non-commercial use, provided that the full name of the document, year and institution are cited.

CONTENTS

Prologue	11
Introduction	15
Technical note	19
1. General aspects	21
1.1 Justification	23
1.2 Cancer-related situation in Spain	24
1.3 Document description	63
2. N.H.S. Cancer Strategy Objectives	69
2.1 Health promotion and protection	71
2.2 Early detection	73
2.3 Adult care	75
2.4 Child and adolescent care	77
2.5 Palliative care	78
2.6 Quality of life	80
2.7 Research	81
2.8 Strategy Evaluation	82
3. Technical recommendations supporting the Strategy	97
3.1 Health promotion and protection	99
3.1.1 Background information	99
3.1.2 Standard	113
3.1.3 Objectives	113
3.1.4 Critical points	115
3.1.5 Actions	116
3.1.6 Examples of good practices	121

3.2 Early detection	125
3.2.1 Background information	125
3.2.2 Standards	129
3.2.3 Breast cancer	129
3.2.4 Cervical cancer	137
3.2.5 Colorectal cancer	141
3.2.6 Prostate cancer	147
3.2.7 Skin cancer	147
3.2.8 Lung, tracheal and bronchial cancer	148
3.2.9 Other screening interventions	149
3.3 Adult care	150
3.3.1 Background information	150
3.3.2 Standards	154
3.3.3 Objectives	156
3.3.4 Critical points	157
3.3.5 Actions	160
3.3.6 Examples of good practices	165
3.4 Child and adolescent care	170
3.4.1 Background information	170
3.4.2 Standards	175
3.4.3 Objectives	175
3.4.4 Critical points	176
3.4.5 Actions	177
3.4.6 Examples of good practices	179
3.5 Quality of life	182
3.5.1 Background information	182
3.5.2 Standards	185
3.5.3 Objectives	186
3.5.4 Critical points	186

3.5.5	Actions	189
3.5.6	Examples of good practices	195
3.6	Palliative care	197
3.6.1	Background information	197
3.6.2	Standards	200
3.6.3	Objectives	200
3.6.4	Critical points	200
3.6.5	Actions	201
3.6.6	Examples of good practices	203
3.7	Information systems	207
3.7.1	Background information	207
3.7.2	Standards	208
3.7.3	Objectives	209
3.7.4	Critical points	209
3.7.5	Actions	210
3.7.6	Indicators	212
3.7.7	Examples of good practices	229
3.8	Research	233
3.8.1	Background information	233
3.8.2	Standards	239
3.8.3	Objectives	240
3.8.4	Critical points	241
3.8.5	Actions	242
3.8.6	Examples of good practices	246

ANNEXES

I.	Bibliography	249
II.	Working group members	272
III.	Scientific committee	276
IV.	External reviewers	277
VI.	The importance of the gender perspective in the Cancer Strategy..	278

PROLOGUE

Cancer is one of the most highly prevalent diseases and the leading cause of death in both Spain and the European Union. In our country, cancer causes approximately 90,000 deaths yearly, thus meaning 25.6% of all deaths, the annual incidence of new cases totaling around 162,000 cases. In individual risk-related terms, one out of every three males and one out of every five females in Spain may have cancer at some time during their lives, although the medical advances are managing to significantly lower the death rate and improve the quality of life of cancer patients, it being estimated, in fact, that half of the cancer cases will survive their disease for more than five (5) years.

According to World Health Organization (WHO) estimates, more than 40% of all cancers are preventable. However, the marked increase in some risk factors such as smoking and obesity is contributing to increase the incidence of this disease.

The fast-paced changes in the world environment as a result of the globalization of the markets and the move toward an urban lifestyle are favoring the consumption of prepared foods rich in fats, sugar and salt, as well as tobacco products. The result is the rise in the incidence of cancer and other chronic diseases. Other preventable risk factors are many cancer-causing substances in the environment and the infections caused by the hepatitis B virus and human papillomavirus.

In coherence with the World Health Organization (WHO) approaches, the Ministry of Health and Consumer Affairs is advocating an integrated focus combining cancer prevention and treatment with the corresponding measures for cardioopathies, diabetes, cerebrovascular accidents and other chronic diseases, given that many of these diseases have some risk factors in common, such as smoking, certain diets and physical inactivity, thus requiring similar responses from the National Health System healthcare services.

Within this context, the National Health System Cancer Strategy is a text serving as support for the nationwide coordination of health prevention and promotion plans or programs, means of diagnosis suitable for achieving early cancer detection and progressively more highly effective cancer treatments.

Similarly, one of the objectives of this Strategy is that of increasing the possibilities of epidemiological, basic and clinical research and creating precise tools which will make it possible to evaluate the situation at each point in time and assess the usefulness of the measures which are going to be implemented.

This document has been drafted by experts from all of the cancer-related disciplines, coordinated by Dr. Eduardo Díaz-Rubio, the Chief of the Medical Oncology Department of the “Hospital Clínico” of Madrid, with the participation of technical staff from the Autonomous Community Health Councils and the Ministry of Health and Consumer Affairs. For drafting this document, the actions and plans carried out both in Spain as well as in the European Union and by the WHO, as well as on the part of other organizations including those such as the Council of Europe and the OECD, have been taken into account.

This Strategy forms part of the National Health System Quality Plan and represents a common, combined effort among the Ministry of Health and Consumer Affairs, the Scientific Societies and the Autonomous Communities in order to achieve cancer patient care based on clinical excellence on equal terms nationwide, thus moving forward the necessary cohesion of our health system in benefit of all citizens, regardless of where they live, this being something which shall undoubtedly serve to further strengthen both the quality and cohesion of our National Health System.

By way of this joint endeavor, the healthcare services and professionals working therein now avail of a tremendously important tool for improving the health of the population as a whole and of their patients in particular.

The National Health System Cancer Strategy is going to be a “routing sheet” for the nationwide coordination of health prevention and promotion programs, the diagnostic means suitable for achieving early detection of this disease and the setting

out of progressively more highly effective treatments in coherence with scientific evidence. Similarly, one of the objectives of this Strategy is that of increasing the possibilities of epidemiological, basic and clinical research and creating precise tools which will make it possible to evaluate the situation at each point in time and assess the usefulness of the measures which are going to gotten under way.

I would like to express my appreciation to all those who have taken part in drafting this document aimed at bettering our citizens' quality of life, as the result of their work will contribute decisively to making it possible to improve the quality of the healthcare provided in the National Health System.

José Martínez Olmos
Secretary General of Health

INTRODUCTION

Cancer encompasses numerous diseases differing in their etiology, behavior and response to treatment, and it can be said that many are preventable, that others can be diagnosed early and treated more effectively, that the groups of individuals at greatest risk can be known in certain cases in order so as to provide them with the suitable genetic counseling, that cancer care is demanding a multidisciplinary intervention, that many cases are curable and that, in the worst of cases, the suitable palliative care must be provided, it being absolutely essential that quality be present throughout, and that research programs in all of the aforementioned areas be gotten under way.

Added to all of the above is the need for equity, cohesion and homogeneity in all of the processes implemented, the fittingness of developing a Cancer Strategy at the National Health System level therefore being evident.

When the Minister of Health and Consumer Affairs decided to first undertake the tasks aimed at preparing a technical document on Cancer, the first action taken was that of conducting a study on the current status of cancer in Spain which would serve as a basis for the National Health System Cancer Strategy. The Environmental Epidemiology and Cancer Department of the National Epidemiology Center of the “Instituto de Salud Carlos III” was placed in charge of studying the incidence, prevalence and mortality for this group of diseases based on the survival data from the European Eurocare III Program.

The Strategy takes in a total of seven priority lines of action: health promotion and protection, early detection, adult care, child and adolescent care, palliative care, quality of life and research. An analysis has been made in each one thereof concerning the existing records and the current status of the situation, the existing critical points, the objectives to be achieved, the actions to be carried out and evaluation indicators having been set out. Similarly, examples of good practices are provided with the intention of their serving as references.

Each line of action in this strategy was dealt with by a group of experts coordinated by a moderator of well-known standing and recognized integrating skills. Representatives from the scientific societies of the different disciplines entailed and social agents became involved in these groups. A total of nearly one hundred experts took part in the working groups, in addition to a similarly large number having been involved as external advisors.

In a first stage, following numerous meetings, a total of 60 objectives, 152 actions and 50 indicators were defined, based on which a prioritizing process employing a highly stringent methodology was then undertaken to then finally come to propose 20 objectives, 37 actions and 20 indicators.

Consensus has been the key to this work at all times, without any personal or institutional dissonances have arisen, which was of prime importance in order for this document to be of the utmost technical precision. The success achieved undoubtedly lay in all of those involved having fully comprehended the magnitude of the problem and the drafting of the Strategy having revolved around patient care above and beyond professional interests.

Following the agreement reached between all of the Autonomous Communities and the Ministry of Health and Consumer Affairs, the NHS Cancer Strategy was approved on March 29, 2006 by the National Health System Interterritorial Council. Following the approval thereof, the most important aspect was then undertaken, which was that of implementing the Cancer Strategy approved by all. The first stage necessary was that of its dissemination, which we considered to be highly important in order to make the Strategy known throughout the entire National Health System, as the implementation thereof falls to the entire National Health System as a whole. Next, the most appropriate mechanism for monitoring the progress of the Strategy was set out in detail for the purpose of evaluating and analyzing how this Strategy is being carried out as well as proposing any possible changes which is may be advisable at each given point in time.

The objectives set out in the Cancer Strategy are aimed, based on scientific evidence, to lower the cancer incidence rate, mortality and improve cancer care quality. This entails reducing the existing inequities and unwarranted variations in the risk of having cancer, in access to the preventive services and in accessing quality clinical services.

We are certain that the implementation of this Strategy is going to afford the possibility of lowering the cancer mortality and incidence figures whilst also creating a more suitable care-providing environment committed to quality at all levels. This Strategy will also mean backing and fostering clinical, basic, epidemiological and applied cancer research and will most certainly be a starting point from which suitable information systems may be attained.

I would like to express my sincerest thanks to all those individuals and institutions who have taken part, as they are the ones having made it possible for this Strategy actually to exist. I would also like to make special mention of the help provided by all of the Autonomous Communities as well as by the Ministry of Health through the Directorate General of Quality.

I have been proud and honored to have had the opportunity to coordinate this work, and although the work done may seem to have been arduous at first glance, I must say that it has actually been easy due to the extraordinary collaboration which I have found everywhere at all levels amongst all those involved. This has been a gratifying endeavor in which consensus has reigned throughout this entire endeavor.

Eduardo Díaz Rubio
NHS Cancer Strategy Coordinator

TECHNICAL NOTE

This document is comprised of three well-defined parts:

The first part – General Aspects -, which deals with the overall situation of cancer epidemiology in Spain and the justification of the Strategy (p. 21-68).

The second part – The National Health System Cancer Strategy Objectives - , which details the Strategy objectives, actions and evaluation system approved by the National Health System Interterritorial Council on March 29, 2006 (p. 69-95).

And the third part – Technical Recommendations Supporting the Strategy-, which sets out a number of possible objectives, standards, actions and indicators as a supporting document for those healthcare institutions involved in drafting Cancer-related plans or programs (p. 97-247).

1. GENERAL ASPECTS

1.1 JUSTIFICATION

General Health Law 14/1986 of April 25th sets forth under Article 70 thereof that general healthcare coordination shall include the determination of common minimum purposes or objectives concerning health promotion, prevention, protection and healthcare..., as well as generally setting out common, basic minimum criteria for the evaluation of the effectiveness and output of the health programs, centers and services.

This law also sets forth that the State and the Autonomous Communities may set out joint strategies which, when involving all thereof, shall be established within the National Health System Interterritorial Council.

Apart from the above, the most recent international experience suggests that one good way of undertaking these joint actions can be the drafting of strategies on the most relevant diseases for the purpose of achieving a homogeneous focus within the scope of the National Health System.

These strategies must set out objectives, actions and recommendations based on scientific evidence and on the good practices available within the scopes of the promotion, prevention, clinical handling, rehabilitation and social reinsertion, information systems and research. These strategies must be drafted with extensive participation of the scientific societies and other social agents and must be revised periodically.

The main guiding principles of the Cancer Strategy are solidarity, equity and participation for the purpose of achieving the reduction of inequities, the promotion of health and of healthy lifestyles and care quality.

In this regard, each Autonomous Community shall implement to a greater or lesser degree those elements of this document regarding which a consensus has been reached as to their being the most effective and having the greatest impact.

Experts from all of the disciplines related to cancer and an Institutional Committee comprised of representatives from all of the Autonomous Communities have taken part in drafting this document.

The technical work of the Cancer Drafting Committee began in April 2003, having given rise to an excellent preliminary technical document based on which, in the summer of 2004, work was started on redefining the Strategy and on implementing a proven methodology for the prioritization of objectives, activities and indicators.

The result of this work was 19 objectives with the corresponding recommendations and proposals of actions and evaluation indicators. This document is completed with a fuller-ranged, more highly detailed technical proposal which may serve the Autonomous Communities which so deem fitting, as a supporting text for the drafting of their Cancer Plans or Programs.

1.2 CANCER SITUATION IN SPAIN

Cancer is one of the major health problems in the developed world, the negative impact of which has a bearing particularly on the most disadvantaged groups of individuals. The last twenty years have been witness to true progress in fully understanding and handling cancer. As of the early nineties, the frequency of deaths caused by cancer has been progressively decreasing at an average rate of 0.7% annually. This progress has led to global figures nearing 50% cured, defined functionally as survivals exceeding five years. In any case, despite real progress having been made, there is clearly a need of advancing toward a final goal, which can be no other than that of preventing and curing all forms of cancer.

Cancer is one of the most highly prevalent diseases in Spain and in the European Union. Recent statistics estimate the number of newly-diagnosed cancer cases in the European Union at 1,300,000 per year, the deaths totaling 837,000 in number. In Spain, cancer is the leading cause of death: approximately 90,000 deaths yearly, meaning 25% of all deaths.

In the year 2000, 91,623 people (57,382 males and 34,241 females) died of cancer in Spain, having meant 25.6% of all deaths (Instituto de Salud Carlos III, *Situación del cancer en España*, June 2003).

In our country, the annual incidence of new cases is around 15,000 cases. Half of these Spaniards survive their disease for more than five years. In terms of individual risk, one out of every three Spanish males and one out of every five Spanish females will be diagnosed with cancer at some time in their life.

Although the cancer survival rate has significantly improved in our country over the past twenty years, the drafting of a NHS Cancer Strategy means an opportunity for optimizing cancer prevention, diagnosis and treatment within the scope of the healthcare organization and also for researching and evaluating the advances achieved.

Apart from the above, there are some major social differences with regard to cancer incidence and some major geographical differences with regard to results, mortality, procedures and care within the same groups of diseases. Hence, the high degree of variability of the release rate and of the average lengths of stay for oncological hospitalization among Autonomous Communities, although the available information may entail comparability-related problems (Instituto de Salud Carlos III, *Situación del cancer en España*, June 2003).

At the same time, Andalusia, Catalonia, Valencia, Navarra, Galicia, Castile and Leon and the Basque Country have drafted Oncological Plans or Cancer Care Strategies. And there are organized, effective population screening programs, as well as records of proven quality. Out of the interrelation of all these efforts and mutual collaboration, a boost and stimulus for achieving the common objectives sought is to be expected. The NHS Cancer Strategy has benefited from this experience and from these efforts. In turn, it may serve as support for the Autonomous Communities which are in the process of drafting their own plans.

Analysis of the cancer situation in Spain

Apart from the above, the Instituto de Salud Carlos III, through a working agreement with the Ministry of Health and Consumer Affairs, has drafted a report on the current situation of this disease (incidence, prevalence and mortality) and care demand and resources which arise as a result thereof, from which the data presented herein has been taken.

Mortality

In absolute terms, cancer is the leading cause of death in Spain, totaling 91,623 deaths in 2000, meaning 25.6% of all deaths (Table 1.1).

TABLE 1.1 TEN LEADING CAUSES OF DEATH. SPAIN, 2000.

	Cause	No. deaths	Raw rate	Adjusted rate (*)	Percentage of total
	All causes	357,788	906.58	623	
1	Malignant tumors	91,623	232.16	173.45	25.6
2	Heart diseases	77,237	195.71	127.56	21.6
3	Cerebrovascular diseases	36,420	92.28	57.49	10.2
4	Chronic lower respiratory tract diseases	16,573	41.99	26.17	4.6
5	Accidents (inadvertent injuries)	11,661	29.55	25.73	3.3
6	Diabetes mellitus	9,232	23.39	14.79	2.6
7	Influenza and pneumonia	8,278	20.98	13.08	2.3
8	Chronic liver disease and cirrhosis	5,137	13.02	10.88	1.4
9	Nephritis, nephritic syndrome and nephrosis	5,634	14.28	8.98	1.6
10	Alzheimer's disease	5,381	13.64	8.04	1.5

(*) Adjusted rates per 100,000 inhabitants (standard European population).

Among all age groups as a whole, cancer is the leading cause in males (57,382 deaths) (Table 1.2). In females (34,241 deaths) even though it is ranked second after cardiovascular diseases, cancer displays a truncated adjusted rate (for the 35-64 age group) three times higher than cardiovascular diseases and causes the high number of potential years of life lost.

TABLE 1.2 NUMBER OF RECORDED DEATHS FOR THE 10 LEADING CAUSES OF DEATH, BY GENDER. SPAIN, 2000.

		All ages	
		Males	Females
1	Cancer	57,382	Heart disease 40,903
2	Heart disease	36,334	Cancer 34,241
3	Cerebrovascular disease	14,931	Cerebrovascular disease 21,489
4	Chronic respiratory disease	12,197	Diabetes 5,686
5	Accidents	8,524	Chronic Respiratory disease 4,376
6	Influenza/Pneumonia	4,127	Influenza/Pneumonia 4,151
7	Diabetes	3,546	Alzheimer's disease 3,622
8	Cirrhosis	3,538	Accidents 3,137
9	Nephritis, etc.	2,764	Nephritis, etc. 2,870
10	Suicide	2,534	Arteriosclerosis 2,749

Analyzing the deaths by age, gender and cause, in the year 2000, cancer is the most frequent cause of death in males and females in the 40-79 age group and is also for females in the 20-39 age group.

In mortality-related terms, tumors are the major cause for males, lung cancer, colorectal and prostate cancer all exceeding 5,000 deaths/year, whilst such a high figure is totaled among females only for breast tumors and colorectal cancer (Table 1.3).

TABLE 1.3 NUMBER OF RECORDED DEATHS FOR THE 10 LEADING MALIGNANT TUMORS, BY GENDER. SPAIN, 2000.

		All ages	
		Males	Females
1	Lung	15,432	Breast 5,663
2	Colorectal	6,448	Colorectal 5,184
3	Prostate	5,448	Poorly-defined tumors 2,629
4	Stomach	3,741	Stomach 2,340
5	Poorly-defined tumors	3,300	Pancreas 1,920
6	Bladder	3,189	Lung 1,876
7	Pancreas	2,069	Uterus 1,800
8	Oral cavity and pharynx	1,833	Ovary 1,755
9	Larynx	1,768	Leukemias 1,255
10	Primary liver	1,722	NHL 1,101

Over the past ten years, cancer mortality among Spanish males has undergone a statistically significant average 0.10% annual increase. (Fig. 1.1)

This increase is due mainly in the rise in the colorectal cancer mortality and, to a lesser degree, to the rising trend in the mortality due to cancer of the pancreas, central nervous system tumors, non-Hodgkin lymphomas, multiple myeloma and kidney cancer (Fig 1.2). Some localizations show a clear drop over the past ten years: stomach cancer, larynx cancer, bone cancer, malignant non-melanoma skin tumors, testicular cancer and Hodgkin lymphoma. It is interesting to find that lung cancer is finally showing signs of stabilizing in our country over recent years. Lastly, the marked increase found in localizations conventionally considered to be infrequent: pleural cancer, skin melanoma and multiple myeloma, with average percentage increases of nearly 3% or above annually stand out particularly.

In females, during the nineties, the cancer mortality has progressively decreased significantly by an average 0.53% annually (Fig. 1.3)

FIG. 1.1 MORTALITY TREND IN SPAIN BY MAJOR CAUSES. MALES, 1975-2001.
Rates adjusted to European standard population

Cases per 100,000 inhabitants

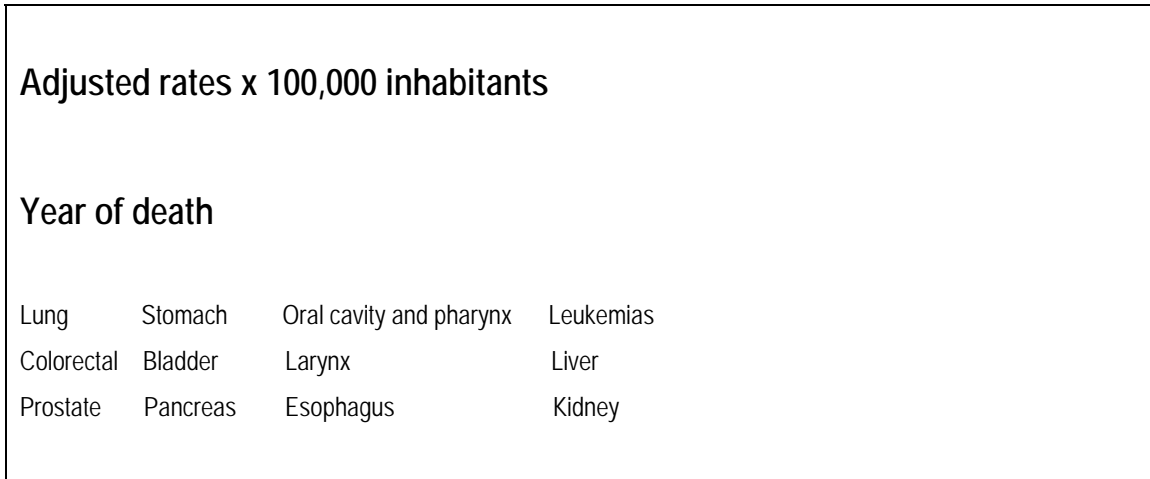
Year of death

Malignant tumors Respiratory tract disease Congenital abnormalities External causes
 Cardiovascular diseases Digestive tract diseases Perinatal Poorly-defined causes

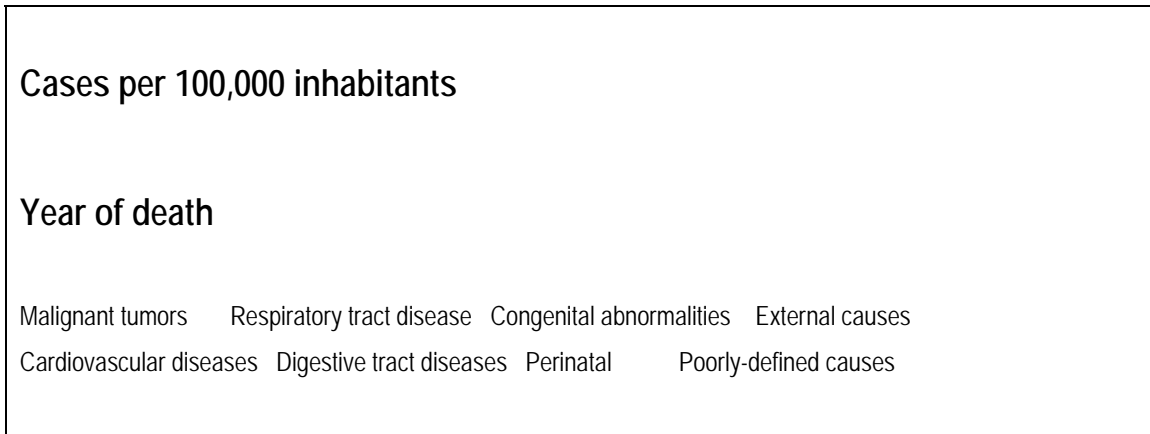
Source: National Epidemiology Center, "Online monitoring of cancer and other causes", <http://cancer.isciii.es>

This drop is due to the decrease in the mortality due to breast cancer, which is decreasing at a rate of 1.4% annually, and to mainly stomach, small intestine and liver tumors (Fig. 1.4). Unlike that stated in males, lung cancer mortality is rising fast among Spanish women, by 1.75% annually. The mortality due to pancreatic cancer, ovarian cancer and malignant tumors of the central nervous system is rising among women, whilst that due to Hodgkin lymphomas and malignant non-melanoma skin tumors is decreasing. Lastly, non-Hodgkin lymphomas, myeloma, skin melanoma and soft tissue sarcomas are showing 1.8% increases in the mortality rate.

FIG. 1.2 MORTALITY TREND IN SPAIN BY MOST FREQUENT TUMOR LOCALIZATIONS IN SPAIN. MALES, 1975-2000.



**FIG. 1.3 MORTALITY TREND IN SPAIN BY MAJOR CAUSES.
FEMALES, 1975-2001.
Rates adjusted to European standard population**



Source: National Epidemiology Center, "Online monitoring of cancer and other causes", <http://cancer.isciii.es>

FIG. 1.4 MORTALITY TREND IN SPAIN BY MOST FREQUENT TUMOR LOCALIZATIONS IN SPAIN. FEMALES, 1975-2000

Adjusted rates x 100,000			
Year of death			
Breast	Lung	Leukemias	Bladder
Colorectal	Ovary	CNS	Myeloma
Stomach	Pancreas	NHL	Kidney

Incidence

The data shown in Table 1.4 is based on the incidence and mortality data in those provinces having cancer registries. This table provides an estimate of the yearly number of cases of different malignant tumors at the nationwide level, their 95%

TABLE 1.4 ESTIMATE OF ANNUAL CANCER INCIDENCE IN SPAIN FOR THE 1997-2000 PERIOD

Tumor localization	Males			Females			Both genders
	Cases	95% CI	AR	Cases	95% CI	AR	Total Cases
All, except skin	97,050	69,560-132,927	448.08	64,977	49,526-83,465	247.19	162,027
Colon and rectum	14,204	9,977-19,753	63.58	11,461	8,152-15,679	39.01	25,665
Lung	16,690	12,271-22,084	77.40	2,131	1,455-3,036	8.07	18,821
Breast	15,979	10,508-23,586	67.06	15,979			
Bladder	12,727	6,441-23,121	58.06	1,750	1,371-2,201	5.56	14,477
Prostate	13,212	6,245-24,524	56.29	13,212			
Uterus and cervix	7,164	4,120-11,657	31.92	7,164			
Stomach	2,896	1,964-4,881	12.76	3,454	1,752-6,225	11.42	6,350
NHL	3,253	1,868-5,280	15.25	2,209	1,696-2,846	8.19	5,462
Larynx	3,705	2,034-6,248	18.31	852	54-3,897	3.66	4,557
Encephalon	1,954	953-3,650	9.56	287	194-410	0.97	2,241
Liver	3,081	2,233-4,158	13.85	1,309	807-2,025	4.02	4,390
Leukemia	2,436	1,873-3,104	11.15	1,852	1,429-2,361	6.75	4,288
Pancreas	1,919	1,449-2,516	8.87	1,675	1,247-2,238	5.30	3,594
Esophagus	1,512	1,319-1,730	7.46	257	1600-406	0.89	1,769
Kidney	1,441	374-3,923	6.71	1,189	771-1,772	4.59	2,630
Melanoma	1,283	597-2,406	6.14	1,785	1,231-2,543	7.26	3,068
Hodgkin	890	386-1,773	4.23	528	244-1,009	2.29	1,418
Myeloma	795	384-1,471	3.54	769	532-1,603	2.54	1,564
Ovary	2,997	1,735-4,870	12.31	2,997			
Thyroid	456	48-1,776	2.22	1,278	205-4,246	5.69	1,734
Gallbladder	696	497-944	3.06	1,542	761-2,804	4.52	2,238
Testicle	820	60-3,706	3.85	820			

confidence interval and the rate adjusted for Spain. The number of cases/year of cancer estimated for the 1997-2000 period is of 162,000, a total of 25,600 cases of which would be colorectal carcinomas, the most frequent tumor of all in absolute terms. The second most frequent tumor is lung cancer, with 18,800 new cases, followed by breast cancer in females, entailing 15,979 cases.

It is important to note the increase the incidence of cancer is undergoing according to the data from those records which have time series (Fig. 1.5)

FIGURE 1.5 ADJUSTED INCIDENCE RATES IN THE SPANISH RECORDS AND ESTIMATED FOR SPAIN



The records of Navarra and Zaragoza are the oldest in our country and are therefore of the greatest time series. Hence, the adjusted rates for all tumors (except skin) in Navarra within the 1983-1986 and 1993-1997 periods have increased by 21.6%

in males and by 15.4% in females and to the same extent in Zaragoza (19% in both sexes). Within the same period, the lung cancer rates in males have risen in both records by around 18%, the behavior however differing in females (Navarra 19% and Zaragoza 0.8%), showing differences in the patterns of starting smoking among women in both provinces. For colorectal cancer in males, the increases are 46% and 43% in Navarra and Zaragoza, respectively, and 18% and 29% in females (Figures 1.6 and 1.7).

The Rioja has an Autonomous Community Population Base Cancer Record. The incidence for 1993 was of 1011 new cancer cases. Gross rate among males of 479.69 /100,000 and of 289.62 /100,000 in females. In 1994, the incidence was of 945 new cases, gross rate in males of 413.03/100,000 and of 305.41 / 100,000.

The Autonomous Community of Cantabria also has a population-based tumor registry, the Cantabrian Tumor Registry (CTR). The incidence of new cancer cases in 1997 was of 2,437 and of 2,335 in 2001. The gross rate per 100,000 inhabitants in 1997 being of 588.06 in males and 342.34 in females, and of 551.21 in males and 323.25 in females for 2001.

FIGURE 1.6 CANCER INDICIDENCE TREND IN NAVARRA, 1973-1999. NOT INCLUDING NON-MELANOMA SKIN CANCER. Rates per 100,000 adjusted to world population.

Rate

Five-year periods

Males

Females

FIGURE 1.7 TREND OF MOST FREQUENT TUMOR LOCALIZATIONS, BY GENDER, IN NAVARRA, 1973-1999

Rates per 100,000 adjusted to the world population.

FEMALES

Rates x 100,000

Five-year periods

Breast Stomach Uterus Colon/Rectum Ovary

MALES

Rates x 100,000

Five-year periods

Lung Stomach Prostate Colon/Rectum Bladder

Survival

Cancer patient survival rates measured as the percentage of cases which manage to survive for a pre-established length of time (i.e. one, three, five years) is the most important indicator of the effectiveness of the healthcare system in the fight against cancer. This indicator reflects to what extent the cases are diagnosed at a potentially-curable stage and the degree of effectiveness of the treatment procedures. The EURO CARE-1, 2 and 3 projects provide information on the overall survival of cancer patients in Europe. EURO CARE has entailed the follow-up of all of the cancer cases included in the participating European cancer registers, all of which are population-based registries, thus minimizing the possible screening biases. The data provided in this section are related to the EURO CARE-3 results, a study which included the nearly 1,800,000 patients with cancer from the participating registries which were diagnosed within the 1990-1994 period. The estimates for Spain are from the cancer registries of the Basque Country, Granada, Gerona, Mallorca, Navarra and Tarragona. Taking into account the year in which the data in question was recorded, it would be possible to expect the current survival rate to be higher, especially for those tumors with great possibilities of responding to treatment.

In Tables 1.5 and 1.6, the relative survival rate is provided (adjusted by other possible causes of death) for the different tumor localizations at 1, 3 and five years according to the aforementioned project.

By comparing these percentages to those found in the previous project (EURO CARE-2), including patients diagnosed within the 1985-1989 period, a significant rise in the overall survival rate is found (rising from 40% to 44% within this five-year period in the case of males and from 52% to 57% in the case of females) in most of the localizations.

TABLE 1.5 CANCER SURVIVAL IN SPAIN BY TUMOR LOCALIZATION
EUROCARE-3 PROJECT FINDINGS. MALES

Cancer	Observations	Survival	Survival	Survival	95% CI
		1 year Percentage	3 years Percentage	5 years Percentage	
Oral cavity and pharynx	2,021	71	42	36	[34-39]
Esophagus	992	33	14	13	[10-16]
Stomach	2,848	44	28	27	[25-29]
Colon/Rectum	5,044	72	57	53	[51-55]
Liver	881	26	13	10	[8-13]
Pancreas	762	15	6	5	[3-8]
Larynx	2,214	88	71	67	[64-69]
Lung	8,789	32	14	12	[12-13]
Skin melanoma	498	90	77	74	[69-79]
Prostate	3,635	86	70	65	[63-68]
Testicle	298	92	89	87	[84-91]
Bladder	3,998	86	77	75	[73-78]
Kidney	999	71	58	56	[52-60]
Encephalon, nervous system	651	34	21	19	[16-22]
Thyroid	122	84	81	82	[68-98]
Non-Hodgkin lymphoma	277	87	79	73	[68-79]
Hodgkin's disease	1,083	69	57	53	[49-57]
Multiple myeloma	350	70	46	34	[28-41]
Leukemia	764	64	50	47	[42-52]
All localizations except skin	36,021	62	47	44	[43-45]

Source: G. López-Abente *et al.*, *Situación del cáncer en España*, Madrid: Ministry of Health and Consumer Affairs, December 2003. Prepared from de Berrino *et al.*, *Survival of Cancer Patients in Europe: the EURO CARE-3 Study*, Annals of Oncology, volume 14, 2003, Supplement 5.

TABLE 165 CANCER SURVIVAL IN SPAIN BY TUMOR LOCALIZATION
EUROCARE-3 PROJECT FINDINGS. FEMALES

Cancer	Observations	Survival	Survival	Survival	
		1 year	3 years	5 years	95% CI
		Percentage	Percentage	Percentage	
Oral cavity and pharynx	322	78	55	52	[47-59]
Esophagus	113	45	26	23	[16-35]
Stomach	1,546	48	33	30	[28-33]
Colon/Rectum	3,709	73	58	55	[53-57]
Liver	349	26	13	12	[8-16]
Pancreas	646	15	7	6	[5-9]
Larynx	42	92	79	80	[65-98]
Lung	773	33	16	13	[11-16]
Skin melanoma	695	98	91	90	[86-93]
Breast	9,814	94	84	78	[77-79]
Cervix	985	86	72	69	[66-72]
Uterus	1,741	89	78	75	[73-78]
Ovary	1,084	66	49	43	[40-46]
Bladder	665	82	73	70	[66-75]
Kidney	465	76	64	61	[56-66]
Encephalon, nervous system	461	37	20	18	[14-22]
Thyroid	437	87	86	86	[81-90]
Non-Hodgkin lymphoma	191	89	80	76	[70-83]
Hodgkin's disease	924	72	60	55	[52-59]
Multiple myeloma	340	74	54	38	[32-44]
Leukemia	539	62	49	44	[40-49]
All localizations except skin	24,699	72	60	56	[56-57]

Source: G. López-Abente *et al.*, *Situación del cáncer en España*, Madrid: Ministry of Health and Consumer Affairs, December 2003. Prepared from de Berrino *et al.*, *Survival of Cancer Patients in Europe: the EUROCORE-3 Study*, Annals of Oncology, volume 14, 2003, Supplement 5.

The costs of cancer in Spain

An estimate of the cost of cancer nationwide and by Autonomous Communities is provided in Table 1.7 in following. The direct and indirect costs, as well as the cancer-related loss of occupational productivity are provided, considering the following:

Direct costs: The consumption of the healthcare system resources. The direct costs include two types: **hospitalization** and **out-patient treatment**.

Hospitalization costs: cost of the hospital stays.

Outpatient treatment costs: specialized out-patient care, consultations, chemotherapy and hormone therapy treatments, drugs and primary care consultations.

Indirect costs: The potential losses of occupational productivity caused by the **mortality** and **morbidity** of the disease.

Estimated mortality-related costs: By means of the assessment of the potential number of years of life lost (PYLL).

Estimated disease-rate related costs: By means of the assessment of the resources which are related to permanent disability (PD) and temporary disability (TD).

Total costs: The direct costs plus the indirect costs.

TABLE 1.7 ESTIMATE OF TOTAL CANCER COSTS (*) IN SPAIN
Data updated to 2003. In euros

	Total cost	Direct cost	Hospitalization (1)	Out-patient treatment	Indirect Cost	Premature death	Permanent disability (PD)	Temporary disability (TD)
Andalusia	258,223,155	187,141,350	4,493,648	142,647,702	71,081,805	34,589,144	32,534,358	3,958,303
Aragon	55,222,690	40,116,251	11,665,658	28,450,593	15,106,439	6,984,181	7,190,117	932,142
Asturias	54,385,230	40,532,927	11,250,605	29,282,322	13,852,303	6,375,310	6,632,507	844,485
Balearic Islands	35,610,075	23,225,942	5,250,538	17,975,404	12,384,133	5,872,672	5,827,350	684,111
Basque Country	55,659,944	62,123,374	14,365,341	47,758,033	43,480,349	21,351,055	19,499,624	2,629,669
Canary Islands	105,603,723	37,019,763	8,464,139	28,555,624	18,640,181	8,949,827	8,617,863	1,072,491
Cantabria	22,494,205	14,776,319	3,337,178	11,439,141	7,717,886	4,016,627	3,302,498	398,760
Castile and Leon	114,244,218	88,945,564	23,896,299	65,049,265	25,298,654	11,860,850	11,901,368	1,536,436
Castile-La Mancha	65,468,983	48,901,030	11,343,883	37,557,147	16,567,953	7,716,315	7,850,403	1,001,234
Catalonia	307,879,651	198,790,493	55,997,632	142,792,863	109,089,158	54,238,810	48,698,847	6,151,501
Com. Valencia	164,872,616	112,687,488	25,853,296	86,834,192	52,185,128	24,965,514	24,965,514	3,027,056
Extremadura	41,150,683	30,681,590	7,552,033	23,129,557	10,469,093	5,096,242	4,778,824	594,027
Galicia	128,279,235	93,348,733	27,146,187	66,202,546	34,930,502	16,375,408	16,429,951	2,125,142
Madrid	239,756,237	149,030,773	39,761,967	109,268,806	90,725,464	46,629,497	39,212,493	4,883,475
Murcia	40,070,822	29,449,513	6,275,134	23,174,379	10,621,309	5,422,835	4,627,576	570,897
Navarra (Foral C.)	24,683,406	16,487,628	3,814,396	12,673,232	8,195,778	4,139,721	3,573,122	482,934
Rioja	12,950,798	9,286,396	2,493,452	6,792,944	3,664,402	1,858,983	1,573,728	231,690
Ceuta and Melilla	3,568,637	2,393,922	368,962	2,024,960	1,174,715	644,181	476,528	54,006
Spain	1,730,124,306	1,184,939,054	303,330,344	881,608,710	545,185,252	267,087,173	246,919,719	31,178,361

(*) Tumors: colorectal, breast, prostate and cervix.

(1) According to MDBS and Hospital Morbidity Survey (Spanish National Institute of Statistics) for the year 2000.

Sources: Antoñanzas *et al.*, *Estudio de costes directos del tratamiento del cancer en España*. Oliva *et al.*, *Informe sobre las pérdidas de productividad ocasionadas por el cáncer en España*.

Cancer prevention

Cancer is a preventable disease with regard to both its onset as well as its negative impacts once it has developed.

In fact, a widely-accepted relationship exists between human exposure to a number of conditions and their developing certain malignant tumors. Some relevant publications have shown that from five to seven out of every ten cancers have a cause which can be linked to human activity, thus defining cancer as a preventable disease to a certain extent (R. Doll and R. Peto, 1981; K. Czene *et al.*, 2002). Primary cancer prevention is aimed at reducing the incidence of this disease by way of reducing exposure to the highest possible degree to a number of factors the presence of which is recognized as necessarily involved in or favoring the onset of this disease. In some cases, these factors are not modifiable or not readily modifiable (such as those related to reproduction). In others, however, it is possible to combat and eradicate this harmful exposure. Given that these risk factors are often related to more than one disease, the different health plans and, more specifically, the plans for controlling cancer have turned this information into a major source of prevention strategies.

Current focus of the primary prevention strategies

Over the past twenty years, some preventive strategies have been developed which have now been evaluated from the standpoint of the decrease in the incidence of tumors and of their applicability, which has made it possible to reach a number of agreements by way of consensus among the different agents committed to improving cancer control, some of the most relevant ones of which are as follows:

- The degree to which any health improvement measure which involves the modification of personal, social and productive habits (C. Stephens *et al.*, 2002) is highly complex is shown. In fact, despite the effort invested by citizens, professionals, institutions and government, the control over certain habits of proven cancer-causing effects such as tobacco, reveals itself to be extremely difficult. Even discouraging, if one takes into account the data available on the actual damage caused. Thus, recognizing the difficulty involved, a tremendous effort and seriousness is necessary at all times in the evaluation and updating of the most ideal strategies, which must be open and multisectorial and in constant change and evaluation.

- Traditionally, the primary prevention strategies have been based on the risk principle, that is to say, on the consideration of the different quantities or concentrations of carcinogenic agents or habits, based on which they could be considered dangerous and therefore preventable. This principle has been substituted for the principle of precaution on defining prevention policies and strategies for cancer and other diseases (N. Myers, 2002).

This means that the recognition of scientific uncertainty as to the damages that a certain degree of exposure is capable of causing mean in practice a behavior which values the potential risk in the planning of preventive actions. This change in approach leads to a number of operating principles, already included under common standards for developed countries, especially for the contaminating agents and tobacco (J. Lubchenco, 1998). Thus, for example, it is not the public or the governmental agencies who must find the proof of the harmlessness of a certain activity. The burden of proof falls to the person in question on carrying out the proof. Proof which must be evaluated by means of an open, informed, democratic process, inviting those potentially affected to the debate and incorporating the examination of a wide range of alternatives to this activity, even non-action (European Environment Agency, 2003).

- This entails it being necessary, when conveying the information to the public at large and designing preventive strategies of an individual or group nature, to clarify toward what risk factors it is necessary to direct the strongest efforts and toward which a less determining attitude must be taken, thus avoiding the dissemination of measures which are effective to only a small degree or which are proven to be ineffective, which saturate the population.

A distinction is then made between a legislative and regulatory level which has a bearing on healthcare policy design and, in general, health and environmental protection, and a level of design of strategies applicable to groups of citizens. The former must tend to be highly restrictive and conservative, and the latter very sound and well-evaluated.

- In this regard, it is advisable not to lose sight of the reference point of the *European Code Against Cancer* recently revised and updated (P. Boyle et al., 2003), the recommendations of which in relation to primary prevention seem to be at this point in time those most soundly related to an actual decrease in the incidence of cancer. In fact, most of the currently-existing cancer-fighting plans of different levels of application, base their primary prevention strategies on these ideas and their better dissemination.

The European Cancer-Fighting Program (EC 96/646) and the subsequent further expansions thereof are a good driving force for the cancer control initiatives and specifically the primary prevention strategies, to meet with the dissemination and the consideration of which they are worthy. The recently-revised European Code Against Cancer (Boyle *et al.*, 2003) includes the best-documented recommendations at this point in time and must continue being a reference point for all those strategies which are designed from the different Cancer Strategies. This is a general basis for carrying out programs which must be adapted to the actual situation of each country and which is specifically stated and specified in each one of the chapters of this document.

If you adopt a healthy lifestyle, you may prevent certain types of cancer and improve your overall health:

- Do not smoke. If you smoke, quit as soon as possible. If you cannot quit smoking, never smoke around non-smokers.
- Avoid obesity.
- Do some moderate physical activity every day.
- Increase your intake of varied fruits, green leafy vegetables and other garden produce; eat at least 5 portions a day. Restrict the intake of foods containing animal fats.
- If you drink alcohol, whether wine, beer or hard liquor, moderate intake to a maximum of two drinks or units daily, if you are a male; and one, if you are a female.
- Avoid overexposure to the sun. It is especially important to protect children and adolescents. Those individuals who have a tendency to burn must protect themselves from the sun throughout their lives.

- Strictly apply the legislation devoted to prevent any exposure to substances which may cause cancer. Follow all of the health and safety recommendations concerning the use of these substances. Apply the radiological protection standards.

There are public health program which may prevent cancer or increase the possibility of curing a cancer following the onset thereof:

- Starting as of age 25, women should undergo testing for the early detection of cervical cancer.
- Starting as of age 50, women should have a mammogram taken for the early detection of breast cancer.
- Starting as of age 50, both men and women should undergo testing for early detection of colon cancer.
- Take part in hepatitis B virus vaccine programs.

These aspects might summarize the current view concerning the attempts to reduce the incidence of cancer and thus its individual and social effects.

Early detection

Breast cancer

The first program for early breast cancer detection among the population in Spain was started in Navarra in 1990 (Table 1.8). In 1991, this program was gotten under way in Asturias. In 1992, other Autonomous Communities followed this initiative: castile-La Mancha, Castile and Leon, Catalonia, the Community of Valencia and Galicia. New programs have progressively been gotten under way. The most recent were started in Extremadura n 1998, on the Canary Islands and in Madrid in 1999 and in the city of Ceuta in 2001, thus completing this activity being extended throughout all of the Autonomous Communities.

TABLE 1.8 YEAR PROGRAMS STARTED, TARGET AGE GROUPS AND PROGRAM COVERAGE BY AUTONOMOUS COMMUNITIES

Autonomous Community	Year programs started	Target age group	Target population	Population covered (%)
Andalusia	1995	50-65	548,216	93.60
Aragon	1997	50-64	101,908	61.21
Asturias	1991	50-64	95,640	100.00
Balearic Islands	1997	50-64	69,141	74.19
Basque Country	1995	50-64	199,828	100.00
Canary Islands	1999	50-64	136,253	83.50
Cantabria	1997	50-64	45,079	100.00
Castile-La Mancha	1992	45-67	190,850	100.00
Castile and Leon	1992	45-65	292,632	100.00
Catalonia	1992	50-69	554,465	100.00
City of Ceuta	2001	45-64	3,662	37.49
C. Valencia	1992	45-69	504,596	100.0
Extremadura	1998	50-64	79,819	100.00
Galicia	1992	50-64	244,956	100.00
La Rioja	1993	45-65	30,984	100.00
Madrid	1999	50-64	417,762	100.00
Murcia	1994	50-69	113,791	100.00
Navarra	1990	45-69	78,791	100.00

Source: <http://www.programascancerdemama.org>, "Situación de los Programas de Cáncer de Mam en España. Año 2002", prepared by this site.

All of the programs include the 50-64 age group as the target population. Some programs, which were started prior to 1994 (Castile-La Mancha, Castile and Leon, C. Valencia, La Rioja and Navarra) deal with women as of age 45. The maximum target age in all of the programs is age 64/65, except Navarra, Catalonia, C. Valencia and Murcia, which include up to 69 years of age, and Castile-La Mancha, which is currently in the process of increasing the age limit.

The number of women targeted by the programs, taking into account the different target age groups in each Autonomous Community in December 2002 was of

3,707,648 women. The population covered by the programs totaled 3,510,625, meaning that 94.69% of the target population had access to this preventive program on that date. Thirteen Autonomous Communities already had 100% coverage of their target population. Andalusia totaled 93.6%; the Canary Islands, 83.5%; the Balearic Islands, 74.19%; Aragon, 61.21% and the City of Ceuta, 37.49%.

The basic screening test that is conducted in the examination departments is the mammogram. Those women who are coming in for screening for the first time have four (4) X-ray images taken (2 X-rays images on each breast). The same is true for subsequent examinations, except in five (5) Autonomous Communities which, on that date, were performing one single plate per breast: Asturias, Castile-La Mancha, C. Valencia, Extremadura and Navarra.

The same length of time between screening processes applies for all of the programs, being every two years, independently of the risk factors. Mammograms being taken more often, referred to as an intermediate mammogram, based on radiological rather than epidemiological criteria.

At this point in time, no aggregate indicators for all of the programs currently under way are available.

The primary care “services portfolio” in relation to early diagnosis of cervical and breast cancer in the former National Health Institute (INSALUD) included as a technical standard (208.3) that “a mammogram be taken every two years on any woman included in service, whose age falls within the 50-64 age group, all inclusive, the findings being recorded on the medical record”. The mammogram coverage in some Autonomous Communities is shown in Table 1.9.

All of these items of data must be interpreted based on the precaution which the constructing the indicator *per se* entails; solely the coverage and participation data for the programs offered for the population will give a full idea of the breast cancer screening activity in Spain.

According to the data from the report “Use of mammography and Pap Tests for the early detection of breast and cervical cancer in Spain” (Health Technologies Evaluation Agency, Evaluation Report No. 34, November 2002), a total of 59.2% of the women 40-70 years of age surveyed report having had at least one mammogram during the two-year period immediately prior to the survey (48% if preventive mammograms are included).

TABLE 1.9 MAMMOGRAM COVERAGE

Geographical area	Coverage (%)	Geographical area	Coverage (%)
Aragon	40.9	Castile-La Mancha	67.0
Asturias	57.9	Extremadura	50.7
Balearic Islands	59.8	La Rioja	89.7
Cantabria	78.8	Madrid	48.1
Ceuta	49.5	Melilla	22.8
Castile and Leon	68.0	Murcia	65.9

Source: Spanish National Health Institute (INSALUD), 2001.

Cervical cancer

A great number of Pap Tests are performed in Spain, although no organized screening programs covering the population are carried out. Many Pap Tests are currently being performed on young women and few on older women, especially those of a lower socioeconomic level (Instituto de Salud Carlos III, *Situación del cancer en España*, June 2003).

The different Autonomous Communities have progressively adopted the recommendations of the international organizations, especially those of the European Union, for setting up programs or protocol for action with the healthcare professionals within the scope of their authorities. Nine Autonomous Communities currently has programs or protocols for the early diagnosis of cervical cancer.

The strategies defined in these programs or protocols are based on opportunistic screening.

A major degree of variability exists both in the age at which a Pap Test being performed is indicated as well as with regard to the length of time between the tests. A recent study conducted by the Technology Evaluation Agency describes the situation of the recommendations with regard to ages and length of time between tests, which is transcribed in following (Technology Evaluation Agency, Report No. 34, 2002).

Most of the programs include women within the 35-65 age range, some beginning at earlier ages, as of the beginning of sexual relations: Extremadura, Basque Country, Canary Islands, Castile and Leon, Catalonia, Navarra, and Murcia (Table 1.10). In the case of Andalusia, the target population is that of women of childbearing within the 15-49 age range.

TABLE 1.10 DESCRIPTION OF THE CERVICAL CANCER SCREENING PROGRAMS IN SPAIN

Autonomous Community	Year started	Type of Program	Scope	Target population	Periodicity
Andalusia	1986	Opportunistic	P.C. & F.P.	15-49	
Basque Country	1999	Opportunistic	P.C. & S.C.	25.59	First two, 1 year and then ever 3-5 years depending on risk
Canary Islands	1995	Opportunistic	P.C. & F.P.	18-65	Following 2 Pap Tests, every 3 years up to age 35 and every 5 years up to age 65
Castile and Leon	1986	Population	P.C.	25.65	First two, 1 year and then every 3 years
Catalonia		Opportunistic	P.C. and women's programs	25.64	Every 3 years
C. Valencia	1995	Opportunistic	P.C. & F.P.	35-65/25-35 depending on risk	Every 3 years
Extremadura	1983	Opportunistic	Program teams	Starting as of first sexual relations up to age 65	First two, 1 year and then every 3 years.
Galicia		Opportunistic	P.C.	35-65	First two, 1 year and then every 5 years
Navarra	2000	Opportunistic	P.C. and Women's Centers	25-65	At risk: 3 or 5 years. High risk: first two, 1 year and then every 3 years
Former National Health Institute (INSALUD) territory		Opportunistic	P.C.	35-64	First two, 1 year and then every 5 years

P.C.; Primary Care S.C.: Specialized Care F.P: Family Planning

The most frequent periodicity is every 3 or 5 years, but many programs recommend that the first two Pap Tests be performed once a year. Practically all of the programs agree in that these tests be conducted within the scope of primary care, women's care programs and family planning.

The primary care "services portfolio" in regard to early diagnosis of breast and cervical cancer in the former National Health Institute (INSALUD) included as a technical standard (206.1) that "all women within the 35-64 age range must have this test performed and the findings (whether or not normal) on the medical record for: A) First two consecutive Pap Tests (exfoliative with Papanicolau tincture) spaced one year apart. B) a Pap Test every five years from age 35 up to 64 years of age". The coverage results in some Autonomous Communities are provided in Table 1.11 below.

TABLE 1.11 PAP TEST COVERAGE

Geographical area	Coverage (%)	Geographical area	Coverage (%)
Aragon	39.5	Castile-La Mancha	25.3
Asturias	18.9	Extremadura	12.8
Balearic Islands	33.4	La Rioja	28.9
Cantabria	40.2	Madrid	37.5
Ceuta	18.2	Melilla	41.3
Castile and Leon	42.6	Murcia	22.5

Source: Spanish National Health Institute (INSALUD), 2001.

Colorectal cancer

To date, solely some pilot studies have been conducted in Spain, most on the initiative of professionals in the hospital care field (Albacete, Canary Islands and Navarra)

One of the latest experiences carried out is the Hospitalet de Llobregat colorectal cancer screening pilot study promoted by the Health and Social Security Department of the Government of Catalonia. This experience may provide information in the near future concerning the acceptance and feasibility of programs of this type.

Some Spanish researchers in the field have joined the European Colorectal Cancer Screening Group which brings together representatives from twelve European countries.

Oncological plans and early detection

Breast cancer

The six Autonomous Communities which have carried out oncological plans (Andalusia 2002-2006, Castile and Leon 2002-2004, Catalonia 2001-2004, Galicia 2002-2005, Navarra 2001, C. Valencia 2002-2006) have early breast cancer detection programs already implemented, the references made in regard to this tumor therefore being related to measures aimed at achieving total coverage and at improving the quality of the different programs. Table 1.12 summarizes the references made in the plans of six Autonomous Communities. The 2003-2007 Murcia Health Plan includes a pilot experience being carried out in a selected area and the evaluation thereof prior to the end of 2005.

TABLE 1.12 EARLY BREAST CANCER DETECTION IN SIX CANCER PLANS

Andalusia	Castile and Leon	Catalonia	Galicia	Navarra	C. Valencia
<ul style="list-style-type: none"> • Achieve accessibility for 100% of women 50-65 years of age. • Active involvement of professionals in primary care. • Set up mechanisms for the coordination and evaluation of the program functioning and findings. • Conduct user satisfaction surveys. • Guarantee a high degree of participation. • Existence of expeditious circuits making response times suitable in the main stages of the program. 	<p>Improvement of quality and coverage of the Early Breast Cancer Detection Program with regard to:</p> <ul style="list-style-type: none"> • Developing guides and protocols. • Promoting monitoring commissions. • Updating mammogram departments to guarantee the 24-month interval. • Guarantee at least 70% participation. • Develop Genetic Counseling departments. 	<ul style="list-style-type: none"> • Finalize the unfolding to all women in Catalonia 50-69 years of age. • Upon completion of this state, assess the advisability of starting screening among the women 45-49 years of age. 	<ul style="list-style-type: none"> • Maintain the European standards, boosting the women's participation. • Expand the target population to all women up to 69 years of age living in Galicia. • Following the European Union recommendations, the length of time once the indication of surgery is established and the first visit following admission be 3 week or less in 90% of all cases. 	<ul style="list-style-type: none"> • Maintain the Breast Cancer Prevention Program. • Increase by 10% the breast tumors less than 1 cm in size in 2002-2008 as compared to those diagnosed within the 1990-1997 period. 	<ul style="list-style-type: none"> • Expand the target population age for the Breast Cancer Prevention Program to 69 years of age. • Improve those aspects which have a bearing not only on survival, but also on the women's quality of life, such as shortening the lengths of treatment. • Provide the psychological support which some women need.

All of the Autonomous Communities except Castile and Leon, which has a population program implemented, point out the need of carrying out opportunistic type early detection activities both on women at risk as well as on the population at large with the development of protocols making it possible to achieve the maximum benefit possible (Table 1.13).

TABLE 1.13 EARLY CERVICAL CANCER DETECTION IN SIX CANCER PLANS

Andalusia	Castile and Leon	Catalonia	Galicia	Navarra	C. Valencia
<ul style="list-style-type: none"> • Early detection program based on the detection of cases with a combined scheme of intervals for performing Pap Tests among women with and without risk factors. 	<p>Improvement of quality and coverage of the Early Cervical Cancer Detection Program with regard to:</p> <ul style="list-style-type: none"> • Implementing the program in 100% of the basic areas. • Developing guides and protocols. • Guaranteeing sufficient participation for the program to be effective. • Carrying out health information and education programs in relation to the cervical cancer risk factors and the measures for its prevention. 		<ul style="list-style-type: none"> • Carry out informative and dissemination activities, especially targeted on risk groups. • Issue recommendations regarding which a consensus has been reached with the corresponding groups of experts for setting out the indications of the cervical cancer screening in the public system before 2006. • Set up a quality guarantee program based on “European Guidelines for Quality Assurance in Cervical Cancer Screening”. 	<ul style="list-style-type: none"> • Implementation of the “Recommendations of the Technical Consensus on Early Cervical Cancer Detection”. 	<ul style="list-style-type: none"> • Increase the primary and secondary prevention actions in groups at risk of cervical cancer. • Update and disseminate the protocol for action for early cervical cancer detection.

Colorectal cancer

All of the plans make reference to the need of carrying out pilot studies which will evaluate the feasibility of this type of screening (Table 1.1.4).

TABLE 1.14 EARLY COLORECTAL CANCER DETECTION IN THE CANCER PLANS

Andalusia	Castile and Leon	Catalonia	Galicia	Navarra	C. Valencia
<ul style="list-style-type: none"> • Conduct pilot studies for evaluating the results of the different screening methods in those areas having the highest mortalities. 	<ul style="list-style-type: none"> • Design an early colorectal cancer detection protocol in the high-risk population according to the findings of the research and scientific evidence available with the involvement of the different levels of care. • Include among the healthy adult health promotion and prevention activities of the primary care services portfolio measures for actively searching out subjects with risk factors and offering screening test on the basis of the protocol 	<ul style="list-style-type: none"> • Pilot study of colorectal cancer screening: evaluate the findings and recommend that they be extended throughout the rest of Catalonia, if applicable. 	<ul style="list-style-type: none"> • High-risk population: <ul style="list-style-type: none"> - Rectosigmoidoscopy once yearly or colonoscopy every two years in persons with familial adenomatous polyposis or Lynch syndrome. - Family history of cancer in first-degree relatives: starting at age 35-40, study of occult blood in feces and rectosigmoidoscopy every 3-5 years. • Population not at risk older than age 50: systematic study of occult blood in feces every 2 years within an organized program. The effectiveness and feasibility thereof must first be valuated. 	<ul style="list-style-type: none"> • Draft and implement an early colorectal cancer detection program in the high-risk population. • Design and promote a pilot colon cancer detection program for the population. • Increase by 20% the Cukes A+B stage tumors by the year 2010 in comparison to those observed in the 1990-1996 period. 	<ul style="list-style-type: none"> • Increase the early diagnosis of colon cancer in groups at risk according to the scientific evidence currently available. • Conduct a pilot study on colon cancer screening in two health districts for the purpose of ascertaining its feasibility, effectiveness and efficiency.

Care

The use of diagnostic and therapeutic procedures varies greatly in the different fields. The factors playing a fundamental role in this variability are the differences in the availability of resources, in the suitability of their use, in the implementation of the clinical practice guides, as well as in the degree of implementation and homogeneity in the patient referral protocols or the practical total lack thereof.

These discrepancies in the use of diagnostic and therapeutic procedures of proven effectiveness are not acceptable, given that they may have an impact on the mortality and disease rates of the patients, it therefore being desirable that these discrepancies be reduced.

One relevant aspect in the quality of cancer care is the variability in medical practice, both in the diagnostic and the therapeutic aspects (Peris, 2001; Pla, 2003). There are two relevant aspects entailed in analyzing this problem: the variability due to the differing treatment focus depending on the specialty caring for the patient first of all, and secondly that linked to the physician's criterion. Treatment in multidisciplinary teams which set out their treatment indications in clinical practice guides based on the best evidence available are the way of making headway concerning this problem.

Equity in oncology refers to access to the diagnostic and treatment technologies, which may differ depending upon the place of residence or the clinical findings. The major problem in oncology care related to accessing the care-providing resources over the past decades has probably been the deficit of radiation therapy equipment widely documented in the different Federation of Spanish Oncology Societies (FESEO) white books (1998, 1999, 2002). Other relevant resource equity-related aspects have to do with the lack of professionals trained in some relevant specialties in providing care for cancer patients. Equity in the availability of specialized resources in the different Autonomous Communities is undoubtedly a pre-requisite for quality care, but does not suffice for similar clinical outcomes, given that another essential aspect is the experience of the clinical professionals, as well as the multidisciplinary integration of the professionals carrying out the treatment procedures (Smith, TC *et al.*, 2001; Institute of Medicine, 1999).

Quality of life

Over the past few years, major advances have been being made in the diagnosis and treatment of cancer, it therefore being possible to now say that, currently, nearly 50% of the patients diagnosed with cancer can be cured. However, scientific advances are being made at the same time in the study and treatment of cancer, and some very important changes are taking place in both the clinical profile of cancer patients and in the therapeutic and care-providing aspects.

The scientific advances made in the field of oncology as well as their rapid dissemination to the mass media are giving rise to both technical and economic “adaptation” problems, at the same time that some major changes are taking pace in the way in which the population at large perceives the problems related to cancer.

The major importance of this problem, given its high incidence and mortality, as well as the greater amount of information of which the population at large avails concerning cancer and its treatments means that:

- A constant stimulus is being generated both for the professionals as well as the health authorities who must meet the demands of the users with regard to technical training and technological and therapeutic availabilities.
- A high degree of social sensitivity is being generated, as a result of which its diagnosis and treatment must be carried out as rapidly as possible by facilitating, to the maximum, the accessibility of the users to the system.
- The current demands of the society in general and of the patients in particular, are progressively greater, the term “quality of life” having become popular. However, the term “quality of life” refers more to user satisfaction than to the quality of the care provided, although quality care is undoubtedly necessary in order for user satisfaction to be achieved.

As a result of all of the above, the NHS Cancer Strategy takes in the quality of life of the patients diagnosed with cancer, the repercussions of the different treatments and their social and occupational adaptation.

Palliative care

Properly tending to the many needs of the patients in advanced and terminal stages and of their family members is an essential part of cancer treatment. The document “National Palliative Care Plan: Bases for Carrying Out the Plan” (Ministry of Health and Consumer Affairs, 2001) stresses the individual’s right to palliative care anywhere, under any circumstance or in any situation. To be successful in implementing this care, this Plan suggests “combining two types of strategies; firstly, basic training in palliative care on the part of all healthcare professionals and, secondly, carrying out specific palliative care programs with trained professionals and the possibility of intervention at all levels of care”.

Since 1991, the year in which the Primary Care Service Portfolio was created as a catalogue of services meeting the health needs (impact) and the demands of users (satisfaction), a service having been included therein to be provided on a compulsory basis, referred to as the “Home Care Service for homebound and terminal patients”. In 1993, a distinction was made, this service then being termed the “Terminal Patient Care Service”. This portfolio service has been progressively improving over the course of time both in its coverage indicators (quantity) and in compliance with minimum technical standards which are those measuring the quality of the service provided and including recruiting standards, symptom control, social-family situation or treatments. The trend in the coverage figures in the former National Health Institute (INSALUD) territory has risen from 44.5% in 1995 to 51.3% in 2001. The evaluation made of this service in 2001 within the former National Health Institute (INSALUD) territory noted a 79% compliance with minimum technical standards, which is revealing of good care quality, the technical standard of this service complied with to the least degree being the evaluation of the social-family situation of the patient.

We have some data available concerning the palliative care activity of the oncology services. It is calculated that 40%-50% of the patients for which care is provided are in the terminal stage, and that over 70% of the time, the oncologist is devoted to palliating (Sanz, 2002). Preliminary results of a recent survey conducted by the Spanish Society of Medical Oncology (SEOM) point out that 56% of the oncology departments avail of resources for palliative care, 42% of the departments avail of specific beds for palliative care, and a specific, individual follow-up is conducted in 57% of the patients by the attending oncologist (Sanz, 2002, b).

According to the Year 2000 Directory of the Spanish Society of Palliative Care (SECPAL), it is calculated that care is provided for approximately 22,000 terminal cancer patients by some specific palliative care team, thus meaning a 25% coverage (Centeno, 2000).

In 2002, the Spanish Society of Palliative Care (SECPAL) identified 294 palliative care resources in Spain, 213 (72%) of which were specific resources. These specific resources include 96 hospital resources and 117 home care resources (Centeno, 2002). Worthy of special note is the major degree of heterogeneity among the different Autonomous Communities.

The care for children diagnosed with cancer

Cancer in children is of different histological, clinical and epidemiological characteristics than in adults, therefore making it necessary for this care to be studied under a separate heading. The incidence of cancer among children in Spain is stable, whilst childhood cancer mortality has decreased thanks to the success of the treatment-related advances. Even so, cancer is the second cause of death among children after the first year of life (M. Pollán, 1998). The predominant histological types in childhood are leukemias, brain tumors and sarcomas, unlike adults, where carcinomas are predominant. In children, the main known risk factors for cancer (smoking, drinking and occupation) are not applicable. In children, the genetic event leading to the development of a cancer is of a much shorter timescale than in adults, especially for those tumors which develop during the first year of life and which are mostly tumors of an embryonic nature. Therefore, it may be supposed that many cases of cancer in children are due to genetic alterations caused while the embryo and fetus are developing.

Knowing what the incidence of childhood cancer is in Spain is the first step toward being able to dimension the healthcare problem posed by this disease. Approximately 140/10⁶ children ages 0-14 are diagnosed with cancer yearly in Spain (Table 1.15). The national childhood tumor registry (National Registry of Childhood Tumors, RNTI/Spanish Society of Pediatric Oncology, SEOP) is the reference point for knowing the epidemiological data of this disease in Spain (R. Peris, 2003).

**TABLE 1.15 ALL CHILDHOOD TUMORS.
AVERAGE INCIDENCE IN SPAIN. 1980-1991 PERIOD. AGE: 0-14 YEARS**

Incidence rates (x 10⁶ children)	All tumors
0-4 years	187.7
5-9 years	112.9
10-14 years	109.6
Raw rate	132.3
Rate adjusted by age	
Boys	154.3
Girls	127.0
Total	141.3

The most frequent cancer during childhood is acute leukemia, followed by brain tumors, non-Hodgkin lymphomas and sympathetic nervous system tumors, as is shown in Table 1.16.

**TABLE 1.16 CASES RECORDED IN THE NATIONAL CHILDHOOD TUMOR
REGISTRY-SPANISH PEDIATRIC ONCOLOGY SOCIETY (RNTI-SEOP).
ALL CASES, 0-19 YEARS (CUTOFF DATE: 7/5/2002)**

Diagnostic groups	0-4 Yrs.	5-9 Yrs.	10-14 Yrs.	>14 Yrs.	Total
Leukemias	1,542	936	545	45	3,070
Lymphomas	382	674	663	82	1,801
CNS tumors	838	888	594	70	2,390
SNS tumors	1,141	163	39	13	1,358
Retinoblastoma	325	23	1	1	350
Renal tumors	586	168	39	13	806
Hepatic tumors	134	10	15		159
Bone tumors	73	285	529	144	1,031
Soft tissue	422	288	214	42	966
Gond/Germ cells	186	67	102	16	371
Carcinomas	48	66	142	16	272
Other tumors	284	157	160	26	627
Total	5,961	3,727	3,043	468	13,199

Getting national protocols under way coordinated by the Spanish Pediatric Oncology Society (SEOP) and the Pediatric Hematology Society (SEHP) and the collaboration thereof in international protocols has determined the survival of the children diagnosed with cancer in Spain being similar to that of our neighboring countries (Fig. 1.8).

FIGURE 1.8 ALL TUMORS. OBSERVED SURVIVAL 5 YEARS FOLLOWING THE DIAGNOSIS IN THE NATIONAL CHILDHOOD TUMOR REGISTRY-SPANISH PEDIATRIC ONCOLOGY SOCIETY (RNTI-SEOP). BY COHORTS OF YEARS OF DIAGNOSIS. 1980-1997 PERIOD (CUTOFF DATE 7/5/2002). AGE: 1-14 YEARS.

Survival years ▲ Survival rises by 19 points (35%) ▼ Risk of death decreases by 41% in the 5 years following diagnosis.
Survival years ▲ Survival rises by 19 points (35%) ▼ Risk of death decreases by 41% in the 5 years following diagnosis.

Research

The past twenty years have been witness to true progress in the handling and understanding of cancer. As of the early nineties, the frequency of deaths caused by cancer has been decreasing at an average rate of 0.7% annually. This progress has led to the current figures nearing 50% cases cured, defined functionally as over five-year survival. In any case, despite true progress having been made, the clearly essential need exists of advancing toward a final goal which can be no other than that of preventing and curing all forms of cancer.

Of the 155,000 citizens affected annually in Spain, half will survive their disease for more than five years. In terms of the individual risk, one out of every Spanish males and one out of every five Spanish females will be diagnosed with cancer at some time in their lives. Lastly, although the cancer survival rate has significantly improved in our country over the last twenty years, based on data from the population tumor registries, there still remains a great deal to be done to improve cancer prevention, diagnosis and treatment within the scope of the healthcare organization, but also within the scope of the field of research.

Substantially raising the survival rate of cancer patients requires discovering and developing new basic know-how and diagnostic, prognostic and treatment methodologies. The contribution which the Spanish biomedical community is making to this research work is limited in comparison to countries of a similar potential our neighboring the developed world.. It is therefore necessary to develop plans for action which will make it possible to catch up with other similar countries in the Western world and thus be able to properly contribute to the common goal of making it possible to prevent and/or cure all cancerous processes.

Scientific-technical scope of the cancer research field

The main object of biomedical research in cancer is to delve deeper into the knowledge of the molecular, biochemical, cellular, genetic, physiopathological and epidemiological mechanisms of this disease and to set out cancer prevention and treatment strategies. Biology, biochemistry, molecular biology, genetics and other related disciplines must join together in studying all of the clinical aspects in this area

so as to be able to expand the knowledge which will eventually make it possible to provide a solution to this highly important human health problem. These fields also include research on new drugs and therapeutic developments, as well as in public health and health services, where epidemiology, sociology and economy are all implemented in combination with one another. Biomedical research is a key tool for bettering the social well-being and improving the quality of life and life expectancy of cancer patients.

The feasibility of biomedical research must be viewed encompassed within a highly competitive, globalized setting requiring an integral approach capable of carrying out coordinated research programs which include groups conducting basic research, clinical research, public health research and applied research conducted mainly by biotechnology and pharmaceutical companies and, to a smaller degree, by public entities and cooperative groups. As examples of this new framework within which cancer research is now encompassed, the information generated with the genome sequence of humans and of other organisms, and the expansion of the technology for the analysis of proteins, gene expression and the variations thereon is making it possible to redefine the organization of the biological system and to delve deeper into the mechanisms involved in developing this disease. The basic knowledge gained by genomic medicine is opening up opportunities for turning this knowledge into the improvement of diagnosis and characterization of the patients and in setting out new treatment targets, the use, toxicity and effectiveness of which must be corroborated by the appropriate clinical tests. By means of these tools, biomedical cancer research must meet the social and clinical demand for more highly personalized, more effective medicine. These advances in basic knowledge will solely be turned into quality of life and well-being for people when they can be applied for improving the prevention, diagnosis and treatment of this disease, which entails the need of coordination with the industrial sector and the cooperative clinical research groups. This requires, among other measures, the creation of integrated centers which will provide space for a sufficient number of basic and clinical biomedical researchers.

Information systems

On one hand, it is necessary to know the current condition of the hospital and population-based cancer registries as a preliminary step toward improving and increasing the possibilities of these registries.

On the other hand, it is necessary to establish the suitable methods and indicators in order to be able to monitor the degree to which the objectives set out in the NHS Cancer Strategy are being carried out and fully achieved.

The information system must be capable of evaluating the carrying out of each one of the lines of intervention in particular and also the Cancer Strategy as a whole. The analysis of this information must be approached at both the level of the NHS and the Autonomous Communities.

1.3 DESCRIPTION OF THE DOCUMENT

1.3.1 Document content and structure

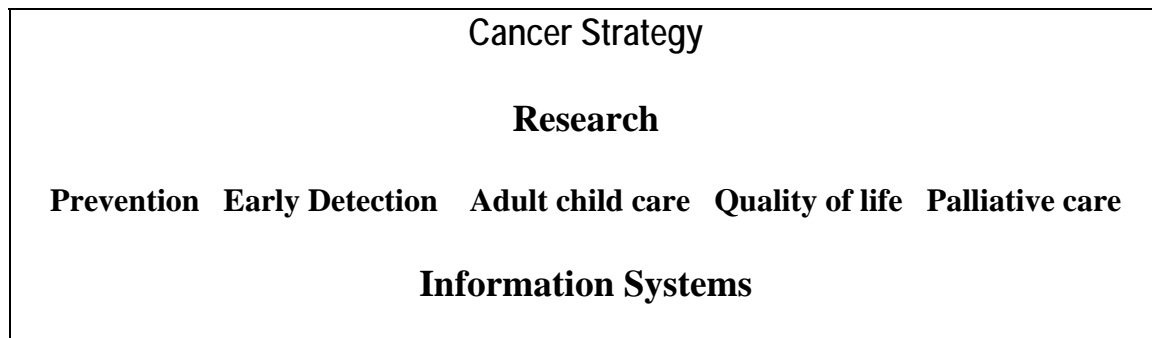
The objective of this document is to define a framework of general action with some care standards and indicators which will guarantee patients proper prevention, care and follow-up throughout any of the stages of this disease.

To this end, standards of care have been agreed upon, with some clear, well-defined *objectives* which will give rise to certain *actions* throughout the process, from prior to the onset of the disease up to the rehabilitation thereof. The evaluation and follow-up *indicators* are also defined.

The NHS Cancer Strategy is related to the following areas of intervention:

1. Primary prevention
2. Early detection
3. Adult cancer patient care
4. Child and adolescent care
5. Cancer patient quality of life
6. Palliative care
7. Information systems
8. Research

The last two of these areas are transversal in nature, given that they refer to aspects dealt with in the previous six sections, as is shown in Figure 1.9.

FIGURE 1.9 NHS CANCER STRATEGY


Indicators and examples of good practices are defined for each one of these areas of intervention, standards, objectives, critical points and actions.

Definition of general concepts

Standard: degree of compliance requirable of a criterion which assures the level of care which must be provided to all individuals. Guarantees the care of a disease equitably for all individuals and patients involved, preventing any discriminations among the population.

The objectives: goals to be achieved, applicable to the entire population on which they are targeted. All of these objectives have been included in the different recommendations of the scientific societies and the authorized institutional entities, having shown themselves to have a considerable impact on reducing mortality and morbidity. The objectives are achievements, not the drafting of tools or instruments, therefore being monitorable, quantifiable and updatable.

This first version of the Cancer Strategy is considered to be a starting point from the actual current situation and must give rise in the future to more highly-committed objectives, it being necessary to progress toward more ambitious goals for the sake of constantly enhancing the quality of the care provided: “Each step must be a goal, and a step likewise”.

The critical points: are aspects, problems or situations which may hinder the objectives being achieved and which, if overlooked, may lead to the failure of the project. These critical points have been pondered and clearly stated from the outset, comprising the thread of the work in each one of its aspects.

The actions: are the general activities which must be carried out in one way or another according to the different organizational criteria of the different Administrations. These actions are indispensable for ensuring that the objectives will be achieved. It must be assured that these actions will be taken in compliance with the recommendations of the clinical guides drafted by the different professional associations, unless a special contradiction were to exist. These actions are subject to the changes inherent to the course and advancement of knowledge and must therefore be updatable.

The indicators: are process or outcome measurements essential for evaluating the effectiveness of the Cancer Strategy. These indicators will provide clear, consistent, updatable information.

The good practices: are examples of initiatives, activities or operating models which have been implemented in Spain or abroad and which are worthy of being considered as a possible point of reference due to the demonstrated effectiveness within their individual context.

1.3.2 Working methodology

Starting plan

Work was begun on drafting the Strategy in 2003, Dr. Eduardo Díaz Rubio having been appointed as the person in charge of the scientific aspects, as many working groups as the number of areas of intervention to be dealt with – eight in all – having been set up and a leader appointed to head each one of the working groups. Each group leader was to be responsible for directing the work done by their group and for drafting the chapter corresponding to their area of intervention. All of the group leaders, along with the person responsible for scientific aspects and the representatives from the Ministry of Health and Consumer Affairs, formed a Technical Drafting Committee.

Each one of the eight working groups was comprised of 8 members: six of whom were officially appointed by the scientific societies having authority over the corresponding area of intervention and two officially appointed by the Autonomous Communities. All of the Autonomous Communities each appointed one representative.

The resulting document was sent to the external consultants designated by the working groups, as well as to the scientific committee representing all of the societies involved and to the Autonomous Community Administrations, where made their contributions.

Redefining the strategy

In 2004, the contents of the pre-existing technical document was then reviewed, it being considered that the orientation and contents developed up to that point in time, even though of excellent quality from the scientific standpoint, should be in keeping with the “STRATEGY” concept within the current framework of transfers and within the authorities of the Ministry of Health and Consumer Affairs. It was proceeded to synthesize the priority objectives, as well as to define indicators related thereto which might objectivize the advances made so that the resulting document might serve as a basis of agreement among the different health administrations.

Designing a working methodology

As a starting point, the methodology entailed forming what was referred to as the “Technical Drafting Committee”, which, starting from the scientific-technical basis

of the previous document, had the mission of prioritizing the minimum common objectives and selecting the indicators making it possible to quantify the progress made.

For this purpose, this Committee was assigned four specific tasks:

- Implementation of a simple system for prioritizing the objectives defined and their corresponding standards. The suggested prioritizing criteria were:
 - ✓ Percentage of individuals affected by the clinical or organizational situation to which the objective is related. This refers to the number of individuals affected by the situation defined in the objective.
 - ✓ Health risk of the user affected by the clinical or organizational situation to which the objective is related. This makes reference to the extent to which the clinical or organizational situation entails harm to health, stated in terms of disease rate, mortality, life expectancy or quality of life.
 - ✓ Data available for measuring the clinical or organizational situation to which the objective is related. This criterion is in relation to the existence of the data necessary for quantifying each situation defined, the accessibility thereof for the individuals who have to evaluate the outcome of the interventions and the degree of complexity involved in attaining the same.
 - ✓ Number of professionals involved in remedying the clinical or organizational situation to which the objective is related. This refers to the number of health system professionals who are involved in remedying the situation set out.
 - ✓ Is there any evidence as to the proposed activities being efficient and/or effective for remedying the clinical or organizational situation to which the objective is related? This refers to the degree of existing evidence concerning the efficiency of the proposed interventions – especially randomized clinical trials – and effectiveness – especially by means of quasi-experimental studies or analytical studies.
 - ✓ Cost of remedying the clinical or organizational situation to which the objective is related. This criterion makes reference to the resources to be mobilized in the Autonomous Communities for remedying a specific

situation in relation not only to the economic cost, but also to the necessary professionals, effort, time, etc.).

- Definition of the phases of implementing the document and of all of the common basic objectives which are intended to be achieved in all of the Autonomous Communities.
- For each objective prioritized, highlight the most highly effective and feasible activity/activities to be gotten under way.
- Similarly, for each objective, select the measurement indicator(s) which quantify the progress achieved. These indicators must be selected based on criteria of validity, reliability and feasibility.

Implementation of a simple system for prioritizing the objectives defined and their corresponding standards in terms of the existing degree of evidence as to the effectiveness of the interventions proposed – especially randomized clinical trials – and effectiveness – by means of quasi-experimental studies or analytical studies.

Evaluation of the complexity and feasibility of the intervention proposed for the clinical or organizational situation to which the objective is related.

The above affords the possibility of selecting a set of objectives, standards and activities, based on the available information/evidence, to be achieved in a short, medium and long-range basis which, in terms of the available resources and of the scope of authorities of the Autonomous Communities, will realistically contribute to improving the quality of the cancer-related interventions and outcomes. The basic criteria employed for said prioritizing were:

- That they be evidence, impact, suitability and feasibility-related criteria.
- That their monitoring/evaluation be possible by means of an information system feasible for the entire NHS as a whole.
- That by offering standards and examples of good practices, they respect the scope of authority of the institutions.

2. N.H.S. CANCER STRATEGY OBJECTIVES

2.1 HEALTH PROMOTION AND PROTECTION

2.1.1 Objectives

Objective 1

The prevalence of ex-smokers in Spain (or in any Autonomous Community) should total above 23%.

Objective 2

The prevalence of smoking in the adult population (>15 years of age) in Spain (or in any Autonomous Community) shall have been reduced to 28% (males 35%, females 25%).

Objective 3

The prevalence of smoking among young people (16-24 years of age) in Spain (or in any Autonomous Community) shall be under 36%.

Objective 4

The Autonomous Communities shall set out regulations governing smoking in public and private by implementing the measures set forth under the Smoking Habit Prevention Law.

Objective 5

In the Autonomous Communities, the interventions of a population-based nature or in risk groups conducive to improving the cancer-related lifestyles and eating habits shall have been gotten under way. One priority will be reversing the trend of obesity in males and females.

2.1.2 Actions

The teaching centers shall implement specific programs for favoring the preventive measures which prevent the smoking habit from being taken up and which encourage healthy living habits.

Smokers shall have access to measures which shall help them quit smoking by means of the suitable interventions in terms of the change study (model of the stages of change): minimal counseling and individualized, specialized assistance.

The groups of healthcare professionals and educators shall be given special consideration in the design of preventive and care-providing strategies by means of specific programs which include the treatment for quitting smoking and the measures of an occupational nature making quitting smoking feasible.

The public and private workplaces (healthcare centers, schools, Government buildings and company workplaces) shall be integrally incorporated into the smokefree spaces network. In the case of public buildings, these criteria shall be included in their contracts, programs and collective bargaining agreements.

The different Autonomous Communities shall be encouraged to draft integral smoking habit plans taking in the legislative, promotion and care measures which have now been found to be the most effective in coherence with the National Smoking Habit Prevention Strategy.

Measures shall be taken on the subject of educating, heightening awareness and promoting healthy lifestyles and living habits targeting professionals and the population at large.

2.1.3 Indicators (See technical information detailed in 2.8)

- Prevalence of ex-smokers
- Percentage rate of quitting smoking
- Percentage rate of smokers over 15 years of age
- Existence of regulations governing smoking in public places
- Existence of regulations governing smokefree centers
- Prevalence of obesity

2.2 EARLY DETECTION

2.2.1 Objectives

Objective 6

Implement breast cancer screening programs organized for the population as a whole, the bases of which are established as follows:

- Target population: 50-59 years of age.
- Women within the 50-65 age range will have access to these programs, and the expansion of the coverage up to 69 years of age shall begin.
- Screening test: mammogram.
- Length of time between examinations: 2 years.

Objective 7

Organized follow-up programs shall be carried out for those persons at a high risk of having breast cancer, colorectal cancer or cervical cancer.

Objective 8

The evaluation of the individual and familial risk of breast cancer and colon cancer shall be promoted, including the indication of conducting a study and genetic counseling for those persons having a high familial or hereditary risk of having this tumor.

2.2.2 Actions

The Autonomous Communities shall carry out the population-based screening programs following the recommendations of the European Quality Control in Mammography Guides.

Total quality assurance programs shall be implemented which take in all phases of the program, particular emphasis being placed on the development of an image quality control system.

From the outset, the programs shall avail of an information system which will afford the possibility of daily management, quality control and periodical evaluation.

A complete follow-up of the cases detected must be assured.

Specific follow-up programs for women must be assured.

Special follow-up programs shall be organized at high risk of having cervical cancer, defined as women from countries having a high incidence rate of this disease and/or subject to a related disease (HIV or other sexually-transmitted diseases).

Specific follow-up programs shall be organized for persons having adenomatous polyps considered to be high-risk or inflammatory intestinal disease.

Genetic counseling shall be provided for those persons having a hereditary risk of having breast or colorectal cancer.

The different levels of care shall actively recruit persons at high risk by means of setting out specific protocols so that a specific screening guideline in terms of the risk thereof may be determined.

2.2.3 Indicators (See technical information detailed in 2.8)

- Coverage of the breast cancer screening programs
- Percentage of women having had a mammogram
- Organized care for patients at risk of cancer
- Map of reference specialized multidisciplinary departments.

2.3 ADULT CARE

2.3.1 Objectives

Objective 9

In those patients having a well-founded suspicion of breast cancer, the diagnostic confirmation process shall begin within the 15 days immediately following the suspicion having first been established*.

Pilot projects shall be carried out with the main objective of achieving the same timeframes for lung and colon cancers (two weeks - from the well-founded suspicion first being established, to the start of the diagnostic process).

Objective 10

The patients diagnosed with cancer shall be treated within the framework of an integrated, multidisciplinary group and by a professional who will serve as a reference point for the patient throughout the hospital care process. The therapeutic decision must be based on the clinical practice guides and protocols of each hospital for each type of tumor. The therapeutic process must end in an overall report which shall be given to the patient.

* The process for the confirmation of the diagnosis in view of a well-founded suspicion of cancer shall be considered to begin when the physician requests a test for the first time or makes a referral in order to confirm the diagnosis.

Objective 11

The time lapse from the therapeutic decision up to the actual start of treatment shall be progressively adjusted to the following recommendations:

- Surgical treatment: recommendable 2 weeks.
- Chemotherapy: recommendable one week.
- Radiation therapy: recommendable 4 weeks (including the planning process).

Objective 12

Those hospitals which provide cancer treatment shall set up tumor committees which will set out the therapeutic decision prior to the treatment and establish an overall treatment plan in which the professional involved in the cancer diagnosis and treatment process shall take part (according to the volume of cases, the tumor committees shall be specific, by tumor location).

Objective 13

The hospital centers which treat patients with cancer shall set out a methodology for evaluating the clinical outcomes of the patients treated in full or in part at that center which will make it possible to evaluate: the survival rate by stage at diagnosis, the percentage of relapses and the surgical death rate at 30 days or within the same hospital admission period.

2.3.2 Actions

Establish clinical criteria of well-founded suspicion of cancer for the main tumors in conjunction with the reference diagnostic test and the priority circuit for performing said diagnostic test.

Draft clinical practice guides which include the diagnostic and therapeutic process by means of the consensus of the professionals and the scientific societies based on the best available evidence. The process must have the support of the medical

technology evaluation agencies and take into account the prior experiences carried out within this scope.

Set up tumor committees at each hospital - if none are already in place - which shall evaluate all of the cases diagnosed and/or treated at the hospital with the participation of all of the specialists involved in the corresponding cancer treatment process. The timeframes between treatments must be evaluated yearly by the committee.

Set out the data collection mechanisms and the clinical results evaluation methodology for the indicators selected. At the end of the period throughout which this plan remains in effect, an audit of medical records shall be considered for the purpose of evaluating treatment timeframes.

2.3.3 Indicators (See technical information detailed in 2.8)

- Breast cancer diagnosis timeframe
- Post-surgical hospital mortality
- Percentage of conservative treatments

2.4 CHILD AND ADOLESCENT CARE

2.4.1 Objective

Objective 14

The care of children and adolescents diagnosed with cancer shall preferably be provided in multidisciplinary pediatric oncology and/or hematology departments which favor psychosocial and educational care as of the point in time of the diagnosis, thus allowing them to continue their maturing development and their education.

2.4.2 Actions

Inform those responsible for the pediatric services/areas of the different Autonomous Communities as to the need of providing care for the children and adolescents (ages 0-18) diagnosed with cancer on a multidisciplinary basis, preferably in oncology or hematology departments possessing proven experience in treating pediatric-age cancer.

Recommend to the scientific societies related to childhood cancer to implement the coordination and communications among all of the pediatric oncology and hematology departments in Spain so that all of the patients will have access to updated treatment protocols.

The health services of the different Autonomous Communities must guarantee the care of the psychosocial aspects and rehabilitation of those children and adolescents diagnosed with cancer.

Set out criteria and protocols for referral to the pediatric hematology and/or oncology departments.

2.4.3 Indicator (See technical information detailed in 2.8)

- Map of reference pediatric oncology and/or hematology departments.

2.5 PALLIATIVE CARE

2.5.1 Objectives

Objective 15

In the case of palliative care, the response shall be agreed to by way of consensus and coordinated among the different levels of care of each healthcare district, including palliative care support teams at the hospitals and in primary care.

Objective 16

In those patients in a situation of advanced terminal cancer, an evaluation shall be made of the needs of both the patient and the patient's family, setting out an interdisciplinary palliative care plan at any level of care.

2.5.2 Actions

The Health Administration shall describe the care process, including identifying the palliative care support resources and structures and their integration by health districts. The composition and duties of these support teams shall be defined at both the primary level and the hospital level.

The primary and hospital care Administrations shall set up an expeditious circuit for emergency care and, were the case to be, for the admission to hospital of the subsidiary palliative care patients.

The administration of each hospital shall assure the availability of beds devoted to palliative care at general hospitals and sociosanitary centers, respecting the privacy and private life of patients and companions.

At the point in time at which a patient is included in a palliative care program at any level of care, the healthcare professionals shall enter the following on their medical record:

- A list of their physical symptoms, emotional situation and communication
- A list of the family's needs, including bereavement care.
- The interdisciplinary treatment plan

2.5.3 Indicators (See technical information detailed in 2.8)

- Compliance with palliative care programs criteria.
- Morphine use.

2.6 QUALITY OF LIFE

2.6.1 Objectives

Objective 17

Provide psychological care for the patient and their family members.

2.6.2 Actions

Promote access to psychooncological care for the patients and their family members who so require, for the purpose of:

- Reinforcing all of the information which may be more likely to lead to any misunderstanding or misinterpretation concerning the disease, its evolution and its treatment.
- Promoting suitable health strategies among patients and their family members for dealing with this disease, the treatments, the professionals, the system as an organization, etc.
- Detecting, evaluating and, wherever applicable, dealing with possible responses with present or future psychopathological potential.
- Helping to positively focus and solve the emotional and personal problems which arise throughout the evolution of the process on a secondary plane to the disease and the care provided.
- Providing counseling as to organization and functioning patterns of the patient's environment, load sharing, prevention of co-dependency, etc.
- Informing patients and their family members concerning the rights to which they have recourse in the event of any possible situation of conflict arising, attempting to help seek positive solutions whenever possible.

2.6.3 Indicator (See technical information detailed in 2.8)

- Percentage of hospitals with functioning departments or professionals providing psychological support.

2.7 RESEARCH

2.7.1 Objectives

Objective 18

Increasing the possibilities of networks of hospitals, centers and/or groups of excellence in cancer research which are interconnected in a coordinated, cooperative manner.

Objective 19

Favoring the creation and consolidation of stable, sound research groups integrated into accredited networks by increasing the possibilities of the allocation of specific resources and spaces for carrying out their work.

2.7.2 Actions

Setting up a stable on-line research structure on cancer in Spain (interautonomic level) with funding mechanisms, periodical evaluation, definite operating rules and exchange of resources, infrastructures and personnel. This structure must take best advantage of the experience of the theme-based cooperative research networks of centers (Theme-based Network for Cooperative Research Among Cancer Centers - RTICCC) and of cancer groups promoted by the Instituto de Salud Carlos III with positive results throughout the past three years, as well as valid models from other countries, such as the U.S. National Cancer Institute's Intramural and Extramural programs and its network of cancer centers located in different states throughout in the United States.

Of particular importance in this regard is maintaining the Theme-based Network for Cooperative Research Among Cancer Center (RTICCC) vertical research lines and horizontal programs (training, tumor banks, tumor registries, biostatistics and epidemiology, genomics and proteomics, molecular diagnosis, non-invasive methods, animal models, new therapies). These programs afford the possibility of making the best use of and sharing nationwide all of the human resources and infrastructures on-line on

clinical, basic, epidemiological, translational and applied research on cancer of recognized standing and proven scientific quality.

Getting integrated cancer research departments/groups under way at all of the hospitals of the different Autonomous Communities which offer full-scale, integral cancer care, which will make an effective, functional interaction among the researchers and the research work at the clinical, basic, epidemiological or care level possible.

Getting this under way must necessarily go along with setting up and implementing a college major in professional research in the Health System, established in accordance with the Instituto de Salud Carlos III guidelines, which will make it possible and justify the work of these in-hospital research departments.

2.7.3 Indicators (See technical information detailed in 2.8)

- Number of group networks and number of approved center networks.
- Number of groups in hospitals or at health centers which, following evaluation, are integrated into approved cooperative networks.

2.8 EVALUATION OF THE STRATEGY

Indicators related to the health promotion and protection objectives (Objectives 1, 2, 3, 4 and 5)

Prevalence of ex-smokers

- **Formula:** $ID = a) \times 100 / b)$, where:
 - a) No. of individuals over age 15 surveyed who report being ex-smokers for at least 10 years.
 - b) Total number of individuals > age 15 surveyed.

- **Definition/explanations:** “Ex-smokers” are considered as being all those who quit smoking at least one year ago.
- **Breakdown:** By Autonomous Communities and by gender.

- **Source of information:** National Health Survey
- **Periodicity:** Biennial

Percentage rate of quitting smoking

- **Formula:** $ID = a) \times 100 / b)$, where:
 - a) No. of individuals over age 15 surveyed who report being ex-smokers for at least 10 years.
 - b) Total number of individuals reporting being non-smokers at the point in time of the survey or rather ex-smokers for at least 10 years.
- **Definition/explanations:** “Smokers” are considered as being all those who smoke tobacco daily, regardless of the amount. On the other hand, “ex-smokers” are considered as being all those who quit smoking at least one year ago.
- **Breakdown:** By Autonomous Communities and by gender.
- **Source of information:** National Health Survey
- **Periodicity:** Biennial

Percentage of smokers over 15 years of age

- **Formula:** $ID = a) \times 100 / b)$, where:
 - a) No. of individuals over age 15 surveyed who report smoking daily at the point in time of the survey.
 - b) Total number of individuals over age 15 surveyed.
- **Definition/explanations:** “Smokers” are considered as being all those who smoke tobacco daily, regardless of the amount.
- **Breakdown:** By Autonomous Communities, by gender and by age groups. An analysis will specifically be made of the prevalence in the 16-24 age group.

- **Source of information:** National Health Survey
- **Periodicity:** Biennial

Existence of regulations governing smoking in public places

All of those regulations published in official Central Government or Autonomous Community gazettes which govern and further expand upon regulations on smoking in public places shall be compiled.

- **Breakdown:** By Autonomous Communities.
- **Source of information:** The official gazettes per se.
- **Periodicity:** Although this be a continuous compilation, a synthesis of the regulations published shall be updated annually (closing on December 31st every year).

Existence of regulations governing smokefree centers

All of those regulations published in official State or Autonomous Community gazettes further expanding upon the rules for considering a center to be “smokefree”, as well as the procedures, if any, for such a designation.

- **Breakdown:** By Autonomous Communities.
- **Source of information:** The official gazettes per se.
- **Periodicity:** Although this be a continuous compilation, a synthesis of the regulations published shall be updated annually (closing on December 31st every year).

Prevalence of obesity

- **Formula:** $ID = a) \times 100 / b)$, where:
 - a) No. of individuals identified as obese according to height and weight.
 - b) Total number of individuals included in the National Health Survey.
- **Definition/explanations:** A person is considered to be obese:
 - 1) If 18 years of age or older, when the ratio between weight and height renders a body mass index (BMI) of 30 kg/m^2 or greater.
 - 2) In the case of young children and adolescents, from 2-18 years of age up, all inclusive, the calculation is made according to specific reference tables by ages and gender (Cole T), Bellizzi MC, Flegal, KM, Dietz WH. Establishing a standard definition for childhood overweightedness and obesity worldwide; international survey). BMJ 2000 (320): 1-6.
- **Breakdown:** By Autonomous Communities, by gender and by age groups.
- **Source of information:** National Health Survey
- **Periodicity:** Biennial

Indicators related to the early detection objectives (Objectives 6,7 and 8)

Coverage of the breast cancer screening programs

- **Formula:** $ID = a) \times 100 / b)$, where:
 - a) No. of women in the 50-69 age range, all inclusive, who are included in an early breast cancer detection program organized on a population base.
 - b) Total number of women in the 50-69 age range, all inclusive.

- **Definition:** A woman is understood to be **included** in said programs when either an offered mammogram has been performed or she has explicitly refused said test. In both cases, this refers to an evaluation timeframe of the past two years.
- **Breakdown:** By Autonomous Communities and by age groups. A distinction shall be made between at least the 50-64 (a.i.) age block, and a specific follow-up shall be made of the evolution of the coverage in the women ages 65-69, all inclusive.
- **Source of information:** Autonomous Community early breast cancer detection programs.
- **Periodicity:** Annual

Percentage of women having had a mammogram

- **Formula:** $ID = a) \times 100 / b)$, where:
 - a) No. of women in the 50-69 age range, all inclusive, who report having had a mammogram within the two years immediately prior to the survey.
 - b) Total number of women in the 50-69 age range, all inclusive, surveyed.
- **Definition:** The term “mammogram taken” includes all those positive responses to the question as to whether they have had a mammogram taken within the last two years, independently of the reason for having had it taken.
- **Breakdown:** By Autonomous Communities and by age groups, carrying out a specific, evolution-related follow-up on the 65-69 (a.i.) age group.
- **Source of information:** National Health Survey (NHS).
- **Periodicity:** Biennial.
- **Comment:** This data shall be available only as of the 2005 National Health Survey findings.

Organized care for patients at risk of cancer

An evaluation shall be made to make certain that all of the cancer care plans drafted by the Autonomous Communities include the criteria and the organization set out for detection and care in accordance with the set objectives for those persons at risk of having the cancers stated in the priorities. An evaluation shall be made as to whether said aspects are explicitly, specifically stated. For breast, colorectal and cervical cancers, the existence of at least the following shall be evaluated:

- the criteria to be employed for the detection and referral of cases
 - the organizational channels for which provision is made
 - the information systems to be used.
-
- **Breakdown:** By Autonomous Communities.
 - **Source of information:** Autonomous Community integral cancer care plans and programs.
 - **Periodicity:** None. They shall be reviewed as they are published or updated. However, an updated status summary shall be made every two years.

Map of reference multidisciplinary specialized departments

The indicator in this case is the existence, as such, of a map of multidisciplinary specialized departments which include the reference genetic counseling organized with a supracommunity perspective in those cases in which it be necessary.

- **Definition/explanations:** The NHS shall be considered to avail of said organized reference map if the circuits for the care in said departments are set out thereon.
- **Breakdown:** Not required, as the entire NHS as a whole is entailed.
- **Source of information:** Ministry of Health and Consumer Affairs.

- **Periodicity:** Biennial confirmation/update.
- **Comment:** Its functioning requires the agreement of the National Health System (NHS) Interterritorial Council.

Indicators related to the adult care objectives (Objectives 9, 10, 11, 12 and 13)

Diagnosis timeframe in breast cancer

- **Formula:** The average, median and maximum values of the timeframe shall be calculated.
- **Definition/explanations:** The “timeframe” is understood as being the time lapse between the date on which the request for a test or for an interconsultation in view of a suspicion of breast cancer is placed and the point in time at which the test/interconsultation is actually carried out.
- **Breakdown:** By Autonomous Communities .
- **Sources of information:** Autonomous Community Primary Care and Specialized Care systems.
- **Periodicity:** Annual

Post-surgical hospital mortality

- **Formula:** $ID = a) \times 100 / b)$, where:
 - a) Number of patients treated surgically within one year’s time for cancer of esophagus, pancreatic cancer, lung cancer or hepatic metastasis who die without being released from hospital or within a maximum 30-day period.
 - b) Total number of patients surgically treated for each one of said processes during that same year.

- **Breakdown:** By each one of the types of tumors mentioned and by Autonomous Communities .
- **Sources of information:** The MBDS at hospital release.
- **Periodicity:** Annual

Percentage of conservative treatments

- **Formula:** $ID = a) \times 100 / b)$, where:
 - a) Patients with breast cancer in one year who undergo conservative treatment of their disease.
 - b) Total number of patients with each one of the cancers mentioned who are treated by means of any therapeutic procedures during that same year.
- **Definition/explanations:** Segmentectomy, quadrantectomy and tumorectomy shall be considered conservative treatments; in short, those treatments which do not entail a radical or modified mastectomy.
- **Breakdown:** By Autonomous Communities .
- **Sources of information:** The MBDS at hospital release.
- **Periodicity:** Annual

Indicators related to the child and adolescent care objectives (Objective 14)

Map of reference pediatric oncology and/or hematology departments

The indicator in this case is the existence, per se, of a map of reference pediatric oncology and/or hematology departments organized with a supracommunity

perspective in those cases in which it be necessary, which makes it possible to guarantee the care that the National health System provides to all citizens who so require:

- **Definition/explanations:** The NHS shall be considered to avail of said organized reference map if the circuits for the care in functioning pediatric oncology and/or hematology departments are set out thereon in accordance with the criteria set forth in Table 5.1 of the document.
- **Breakdown:** Not required, as the entire NHS as a whole is entailed.
- **Sources of information:** Ministry of Health and Consumer Affairs.
- **Periodicity:** Biennial confirmation/update.
- **Comments:** Its functioning requires the agreement of the National Health System (NHS) Interterritorial Council.

Indicators related to the palliative care objectives (Objectives 15 and 16)

Compliance with palliative care program criteria

An evaluation shall be made as to whether all of the palliative care plans or programs include the care and organization criteria necessary for providing care to those in need thereof.

- **Definitions/explanations:** The explicit statement of the following aspects shall be evaluated:
 - Description of the care-providing process.
 - Available resources for caring for these patients.
 - Circuits and coordinating mechanisms among devices.
- **Breakdown:** By Autonomous Communities.
- **Sources of information:** Plans, programs or other documents structured for palliative care drafted by the Autonomous Communities.

- **Periodicity:** They shall be revised as editions or updates are progressively completed by the Autonomous Communities. An updated summary of what currently exists shall however be made biennially.

Use of morphine

- **Formula:** $ID = a) \times 100 / b)$, where:
 - a) Number of defined daily doses (DDD) of morphine (code N021101) dispensed by prescription and/or supplied in hospital.
 - b) Total number of DDD of opiod drugs dispensed by prescription and/or supplied in hospital.
- **Definition/explanations:** Construction of the denominator: The denominator shall be the total consumption (dispensed by prescription or hospital supply), in DDD, of all those pharmaceutical specialties containing the following active ingredients: Buprenorphine (N02AE01) + Fentanyl (N02SB03) + Morphine (N02AA01) + Oxycodone (*) (N02AA05) + Pentazocine (N02AD01) + Petidine (N02AB02).
- **Breakdown:** By Autonomous Communities, by scope of use (community or hospital).
- **Sources of information:** Ministry of Health and Consumer Affairs and Autonomous Community pharmaceutical information systems.
- **Periodicity:** Annual.

Indicators related to the quality of life objectives (Objective 17)

Percentage of hospitals having operating departments or professionals providing psychological support.

- **Formula:** $ID = a) \times 100 / b)$, where:
 - a) Number of hospitals providing cancer treatment which avail of operating departments or professionals providing specific psychological support to these patients.
 - b) Total number of hospitals providing cancer treatment.

- **Breakdown:** By Autonomous Communities..
- **Sources of information:**
 - Component a): Information furnished by the Autonomous Communities.
 - Component b) Ministry of Health and Consumer Affairs (approximation by way of the healthcare center, services and establishments registry and the statistics of establishments operating on a confinement system).
- **Periodicity:** Biennial.

Indicators related to the research objectives (Objectives 18 and 19)

Number of group networks and number of accredited center networks

- **Formula:** Number of approved cancer research networks.
- **Definitions/explanations:** The cooperative theme-based networks are defined as organizational structures formed by the association to the Instituto de Salud Carlos III of a variable set of centers and groups conducting research in biomedicine on a multidisciplinary basis operating under the different Government Administrations or in the private sector and pertaining to a minimum of four Autonomous Communities, the objective of which is that of carrying out cooperative research projects of general interest.
 - The group networks are of a more specific scope, it being necessary to bring together at least five centers.
 - The center networks are broad-scoped as regards the specific subject matter, must also bring together at least five centers, but with at least three groups per center.
- **Level of breakdown:** None, the entire National Health System as a whole is entailed..

- **Sources of information:** Ministry of Health and Consumer Affairs.
- **Periodicity:** Annual.

Number of groups, at hospitals or healthcare centers, which, after evaluation, are integrated into accredited cooperative networks.

- **Level of breakdown:** None, the entire National Health System as a whole is entailed..
- **Sources of information:** Autonomous Communities.
- **Periodicity:** Annual..

Overall Strategy Indicators

Cancer mortalities

- **Formula:** $ID = a) \times 100,000 / b)$, where:
 - a) Number of persons who have died from cancer, by each type of cancer, within one year's time.
 - b) Population for that same year.
- **Definitions/explanations:** Both gross and adjusted rates shall be calculated.
- **Levels of breakdown:** By Autonomous Communities, by tumor groups and by gender.
- **Sources of information:**
 - Component a) National Institute of Statistics death statistics
 - Component b): National Institute of Statistics population projections.
- **Periodicity:** Annual

Cancer incidence rates

- **Formula:** $ID = a) \times 100,000 / b)$, where:
 - a) Number of new cancer cases diagnosed within one year's time.
 - b) Population for that same year.
- **Definitions/explanations:** All of the cases and specific types of tumors shall be registered according to the anatomopathological classification and coding system accepted by the International Agency for Research on Cancer. Both the gross and adjusted rates shall be calculated..
- **Levels of breakdown:** By Autonomous Communities, by tumor groups, by age groups and by gender.
- **Sources of information:**
 - Component a) Population-based cancer registries and the National Childhood Tumor Registry.
 - Component b): National Institute of Statistics population projections.
- **Periodicity:** Annual
- **Comments:** Requiring agreement as to a circuit for communications and remittal of information being reached among the Registries and the Ministry of Health and Consumer Affairs.

Rate of potential years of life lost due to cancer

- **Formula:** $ID = a) \times 1000 / b)$, where:
 - a) Number of years of life lost due to deaths having occurred due to cancer, after 65 years of age and before 75 years of age, for a given year.
 - b) Population ages 0-65 and 0-75, respectively, for that same year.

- **Definitions/explanations:** Both the gross and adjusted rates shall be calculated..
- **Levels of breakdown:** By Autonomous Communities, by tumor groups and by gender.
- **Sources of information:**
 - Component a) National Institute of Statistics death statistics.
 - Component b): National Institute of Statistics projections.
- **Periodicity:** Annual
- **Comments:** Requiring agreement as to a circuit for communications and remittal of information being reached among the Registries and the Ministry of Health and Consumer Affairs.

population-based survival rate, observed and relative at 1, 3 and 5 years.

- **Formula:** For the observed survival: $ID = a) \times 100 / b)$, where:
 - a) Number of cancer patients in a given year which remain alive 1, 3 and 5 years following the diagnosis and treatment of their disease.
 - b) Number of cancer patients diagnosed that same year.

For relative survival:

 - a) Observed survival in cancer patients.
 - b) Expected survival in general population of the same age and gender.
- **Definitions/explanations:** The Hakulinen method shall be employed, and reasons adjusted by age shall be calculated.
- **Breakdown:** By Autonomous Communities, by tumor groups and by gender.
- **Sources of information:** population-based cancer registries, National Childhood Tumor Registry and National Death Index.
- **Comments:** Requires circuits being set up for communications and information among the Ministry of Health and Consumer Affairs Registries, as well as the Index actually being implemented on the part of the Ministry of Health and Consumer Affairs.

3. TECHNICAL RECOMMENDATIONS SUPPORTING THE STRATEGY

3.1 HEALTH PROMOTION AND PROTECTION

3.1.1 Background information

In order of importance by their direct repercussions (rise in cancer incidence) and by the degree of certainty as to their involvement in causing cancer: smoking, certain elements of the diet, nutritional factors, obesity, physical activity, drinking and occupational and environmental exposure must be considered as the major agents.

Smoking

Smoking unquestionably has major implications in increasing the possibilities of having a good number of diseases. It is the main factor responsible for cancer, including lung cancer (85% of the cases of lung cancer being estimated to be caused by smoking) and the cancers of the oral cavity, larynx, pharynx, esophagus, pancreas, urinary bladder and kidney (Schottenfield, 1996). The exposure to environmental tobacco smoke (second-hand smoke or passive smoking) is also considered to be a risk factor for a number of diseases among both children and adults, especially lung cancer (IARC, 2002).

In Spain, the mortality attributable to smoking is estimated at 14% of the total mortality figure, in other words, 56,000 deaths yearly (Banegas *et al.*, 2001). The trend in mortality due to lung cancer and other smoking-related diseases has been a non-stop rising upward trend to date. As far as smoking in Spain is concerned, there was a progressive rise in prevalence up to the maximum figure reached around 1975, having then stabilized throughout a ten-year period, to have then progressively been lowering to date. The pattern by which the smoking habit has spread differs for women, showing a very low degree of smoking up until the seventies, as of which time it has been rising non-stop to date (Fernández *et al.*, 2003). According to the National Health Survey (2003), 34.15% of the males and 22.3% of the females over 15 years of age reported smoking daily.

This fact, in conjunction with the high healthcare and social cost involved, plus the fact of the smoking habit being a preventable risk, have made lowering the prevalence of smoking the main objective of the health policies in Spain, as is set forth under the National Smoking Habit Prevention and Control Plan (2003-2007) and the Integral Ischemic Cardiopathy Plan (2004-2007). It is in keeping with these plans that the objectives, critical points, actions and indicators for the control of the smoking habit have been set out in this Strategy.

The arguments in favor of lowering smoking prevalence are so overwhelming that the role of the governments is tending toward progressively more radical stances. This attitude is favored by citizen pressure on one hand and the social costs on the other, which is making it necessary to resituate the role tobacco undoubtedly plays as an economic agent (taxes, production and employment). This rising concern has resulted in a noticeable advancement in several directions:

a) *Regulatory and legislative advances*

Over the past twenty years, different countries have adopted a number of laws differing in their degree of depth and field of application (French Evin Law of 1991, Royal Decree 192/88 and Royal Decree 1079/2002 in our country). Similarly, the European Union has carried out a vast regulatory endeavor (including directives such as those of July 1998, June 2001 and December 2002). Work has been being done through the WHO since 1994 on an International Anti-Tobacco Treaty (WHO, 2002), as well as a Framework Convention on Tobacco Control (WHO, 2003) being drafted and adopted by the member countries. Without delving any further into aspects unrelated to the objective of this report, the main lines of interest of these regulations revolve around:

- Agreements on tobacco-related tax policy to be implemented.
- Further expansion of the prohibition of smoking in public places.
- Restricting tobacco advertising.
- Improvement of consumer information concerning the effects/composition of tobacco.

However, it must be said that the interest in the implementation of these regulations has varied greatly amongst the different countries (Gilmore *et al.*, 2002), revealing, once again, the difficulty involved in this type of problems in which the healthcare aspect does not always prevail over other aspects. Suits have now timidly begun being filed against the tobacco companies in some individual cases, urged by associations and governments, which are revealing of this aforementioned progressive meeting of more radical stances.

b) *Special plans to combat the smoking habit*

In most of our neighboring countries, these standards have been associated with the implementation of specific anti-smoking plans which have revolved around facilitating the achievement of at least the following five objectives:

- Decrease the prevalence of smokers. A frequent figure in our environment is that of reaching a rate of less than 20% smokers among those over 16 years of age and of 0% among those under sixteen. Special stress is placed on decreasing the percentage of smokers among the healthcare professionals.
- Safeguard the non-smoking population by means of express prohibition or restricting spaces.
- Improvement of the general information on the effects and composition of tobacco.
- Active help for quitting smoking, particularly through the creation and improvement in accessibility to the consultations for quitting the smoking habit and the free dispensing of drugs and nicotine substitutes.
- Special attention placed on the populations at highest risk upon whom the pro-smoking advertising is most being targeted at this time: young people, women and the socially-excluded population.

The different plans for controlling the smoking habit all have certain aspects in common. The first of these aspects is the systematic inclusion of measures which will evaluate the impact of the strategies adopted, given that they are effective to a low degree, and the economic resources for carrying them out are in competition with other healthcare and non-healthcare needs. The second aspect is that they implicitly entail specific strategies for making smoking no longer seem “commonplace” and “normal”,

especially among young people, in an attempt, here once again, to keep ahead of the tobacco company messages (Ministère de la Santé, 2002).

c) *Anti-smoking strategy evaluation*

We avail of literature evaluating the impact of the different measures in terms both of decrease in the number of smokers as well as health improvements. Of all thereof, those having a bearing on the demand through the rise in prices, curbing advertising and specific prohibitions are those giving rise to the best outcomes. Quite eloquently, it is estimated that an overall 10% price rise could mean saving over 10 million deaths (Jha *et al.*, 2000).

The strategies for the implementation of methods for quitting smoking (minimal counseling, specific consultation), as well as the administering of nicotine substitutes are showing some good cost-effective results when compared to other healthcare measures (C. Silagy *et al.*, 1999 and 2002).

The educational strategies for preventing smoking among young people show poor results. The most highly effective are however those displaying a major degree of coherence with the environment (avoiding twofold messages or contradictions), stressing the role of manipulation sought by the tobacco industry and in which a certain reference to fear is present (K. Witte *et al.*, 2000).

Such as the experience in the U.S., a pioneer in this area, has revealed the strategies encompassed within full-range (multisectorial) anti-tobacco plans for action with specific programs taking in most of the vulnerable elements (starting smoking, young people, helping smokers, prohibition of spaces ...) and those having credible financing maintained over time to be more highly effective than the legislative measures (M. Siegel, 2002).

Situation in Spain

The Interterritorial Council of January 2003 rendered approval of the National Anti-Tobacco Prevention and Control Plan (2003-2007), the objective of which is that

of coordinating different actions (legislative, health plans and others) of the fight against the smoking habit in our country. This Plan revolves particularly around:

- Special workplaces (schools, healthcare centers, public buildings and entertainment complexes) as being smoke-free (objective of 95% in 2005) and regulations on smoke-free spaces (70% of companies).
- Unifying criteria for the prohibition of sale (elimination of the sale of tobacco without an I.D., selling individual cigarettes/cigars, packs containing less than 20 cigarettes).
- Prohibition of advertising and sponsorship.
- Setting out tax measures and price rises.
- 2007 objective of 21% ex-smokers and less than 34% smokers among the 16-25 age range.

Diet, obesity and physical activity

Nutritional factors are yet other factors related to cancer prevention.

This aspect is related to diet and its composition, obesity and also physical activity, given that all of these aspects are noteworthy as being closely interrelated. The studies on the effects of diet entail some methodological problems, as diet includes substances of unknown effects, in addition to its components undergoing interactions with one another and with other factors (environmental or genetic) (Chesson *et al.*, 1997). Despite this fact, there are sufficient indications as to cause-effect relationships existing among diet, nutrition and cancer to set out recommendations based thereon to both the policymaking authorities and the population in general.

The data currently available suggests that diet-related aspects cause around one third of all cancer-related deaths. A total of 30%-40% of all tumors in males and up to 60% of all tumors in females are estimated to be diet-related (Doll & Peto, 1996, WCRF, 1997).

The diet recommendation, in conjunction with keeping physically active and having a suitable body mass index could contribute over the course of time to reducing cancer incidence by 30%-40%, especially breast cancer (post-menopausal women) and endometrial, colon, renal and esophageal cancer (ACRF, 1997; WHO-FAO, 2003) (Table 3.1).

Convincing or probable test results are available, according to which diets rich in green leafy vegetables and fruit safeguard against cancers of the oral cavity, pharynx, larynx, and esophagus and against lung, stomach, colorectal, laryngeal, pancreatic, breast and bladder cancer (WCRF, 1997; Key *et al.*, 2002; WHO-FAO, 2003; Riboli, E., 2003).

The evidence of physical activity safeguarding against colon cancer is convincing (Hill, 1999; WCRF, 1997; WHO-FAO, 2003). Just as a major body mass increases the risk of endometrial cancer, obesity increases the risk of breast cancer in post-menopausal women, endometrial cancer, colorectal, renal and esophageal cancer, and the degree of evidence available in this regard is convincing.

A consensus currently exists in the scientific community as to the role played by fat intake as a risk factor, and it is recommended to reduce the total fat intake, especially the intake of saturated fatty acids. Different authors have analyzed the potential impact on life expectancy and mortality, by certain types of cancer, of some of the diet-related preventive measures, concerning which a more convincing degree of evidence exists:

- Diets rich in abundant amounts of varied green leafy vegetables and fruits would prevent 20% or more of all cases of cancer (Van't Veer *et al.*, 2000; Gundgaard *et al.*, 2003; Pomerleau *et al.*, 2003).
- An alcohol intake kept within the recommended limits would prevent up to 20% of the cases of the aerodigestive apparatus, colorectal and breast cancer (WCRF, 1997).
- Stomach cancer is prevented above all by way of proper diets. Colon and rectal cancer is prevented mainly by means of proper diets, by maintaining or increasing physical activity and maintaining proper body weight (WCRF, 1997; WHO-FAO, 2003).

An interesting study revealed the safeguarding effect of following the diet guides on tumors of different localizations. This effect was however lessened and even ceased to be significant when solely the diet-related aspects were taken into account and

a BMI within the range of normal values (18.5-24.9 kg/m²) and regular physical activity were not included in the recommendations.

TABLE 3.1 SUMMARY OF THE EVIDENCE OF THE RELATIONSHIP AMONG DIET, PHYSICAL ACTIVITY, OBESITY AND CANCER

Degree of evidence*	Reduce the risk	Increase the risk
Convincing	Physical activity (colon)	Overweightness and obesity (esophagus, colorectal, breast in post-menopausal women, endometrial and renal) Alcohol (oral cavity, pharynx, larynx, esophagus, liver, breast) Aflatoxin (liver) Chinese-style fish in brine (nasopharynx)
Probable	Green leafy vegetables and fruits (oral cavity, esophagus, stomach, colorectal). Physical activity (breast)	Canned meat (colorectal) Foods in brine (stomach) Very hot foods and drinks (oral cavity, pharynx, esophagus).
Possible/Insufficient	Fiber Soy Fish Omega 3 fatty acids Carotenoids Vitamins B2, B6, B12, folates, C, D and E Calcium, zinc and selenium Photochemical (alliaceae, flavonoids, isoflavones, lignans...)	Animal fats Heterocyclic amines Polycyclic aromatic carbohydrates Nitrosamines

Source: WHO-FAO, 2003.

* *Convincing:* Epidemiological studies with agreeing results (observational, randomized, of cases and controls) of sufficient good quality. The relationship is plausible from the biological standpoint. *Probable:* Epidemiological studies with agreeing results, some with limitations or rendering conflicting results. The relationship is plausible from the biological standpoint. *Possible:* The available evidence comes, above all, from case studies and controls and from cross-sectional studies. Further studies are required. *Insufficient:* Evidence based on a few studies which suggest that a relationship may exist. Further well-designed studies supporting the current evidence are required.

Situation in Spain

Obesity

The most recent results of the 2003 National Health Survey affords the possibility of estimating a 13.32% prevalence of obesity (body mass index, $BMI \geq 30$ kg/m²). The estimates resulting from the SEEDO'2000 study, based on the individual measures of weight and height employing the same criterion place the magnitude of this problem at 13.4% among Spanish males and 15.7% among Spanish females within the 26-60 age range (Aranceta *et al.*, 2003). In the early childhood and juvenile population in Spain, a 15.6% prevalence of obesity has been estimated among males and 11.5% among females within the 2-24 age range in Spain (Serra-Majem, 2001). The comparison of the results of the successive health surveys, always employing the same methodology, reveals a growing trend concerning this problem. This trend has been related to a sedentary lifestyle, changes in the food intake pattern, and with regard in small children, their also not having been breast-fed (Gutiérrez-Fisac *et al.*, 2000).

Diet

The total fat intake in the average diet in Spain according to the results of the eVe study – individual analysis of food intake – is high (Aranceta *et al.*, 2000). In the young childhood and juvenile population, the results of the Kid study suggest that 88% have fat intakes totalling over 35% of the calorie intake, and in 96% of the cases, the intake of saturated fatty acids totals more than 10% of the daily calories. The estimated average intake of fruits and green leafy vegetables (3 servings/day) is far from the recommended five servings daily, totaling around 400 g/day. A total of 88% of the children and adolescents and 56% of the adults within the 25-60 age range do not regularly include the proper amount of fruits and green leafy vegetables in their diet.

Physical activity

A total of 46.6% of Spaniards have a sedentary life (52% of females and 41% males). These figures are excessive both among young people (38%) and older adults (53%), and alarming among females, given that half of the young people and 62% of those over age 65 report not doing any type of physical activity.

Effectiveness of the diet strategies and physical activity

Different institutions and organizations have proposed measures related to diet and physical activity aimed at preventing the most highly prevalent chronic diseases in the developed societies, one of the most important of which is cancer. The World Cancer Research Foundation (WCRF) and the American Institute for Cancer Research (AICR) started an intense program in the nineties aimed at encouraging eating fruits and green leafy vegetables. The European Code Against Cancer also includes this measure.

The European EURODIET project set out some nutritional objectives to be achieved for this same purpose based on the analysis of the diet-related and epidemiological situation (Kafatos and Codrington, 2001). Within the 1999-2001 period, the Spanish Community Nutrition Society coordinated the work of more than one hundred experts in nutrition and public health in the process of setting out the nutritional objectives and diet guides for the Spanish population (SENC, 2001).

The World Health Organization data suggests that in Europe the budget allocated to health promotion strategies by the European Union member countries totals on the average of less than 1% of their healthcare spending (WHO, 1997). Systematic revisions analyzing the effectiveness of the different interventions aimed at promoting healthy eating habits and regular physical exercise have made it possible to identify some characteristics fostering a higher impact on health (Roe *et al.*, 1997; Hillsdon and Thorogood, 1996). One of the outstanding aspects is the need of employing a multidisciplinary focus, using multiple complementary strategies, including actions at the individual, community, environmental, regulatory and policymaking level. The dissemination of information alone is not effective (Stockley *et al.*, 2001).

Nutrition, Physical Activity and Obesity Prevention Strategy

The Ministry of Health and Consumer Affairs drafted the *Nutrition, Physical Activity and Obesity Prevention Strategy* in Spain in 2005 for the purpose of improving the eating habits and promote regular physical activity on the part of all citizens, focusing special attention on prevention during the early childhood stage. The high probability of an obese child growing up to be an obese adult in the future is a proven fact.

The *Nutrition, Physical Activity and Obesity Prevention Strategy* goal is mainly to foster healthy eating and to promote physical activity in order to reverse the rising trend in the prevalence of obesity and thus substantially reduce morbidity and mortality attributable to chronic diseases.

Drinking

The relationship between drinking alcoholic beverages and developing malignant tumors is well-known, although its importance in overall terms is less apparent than smoking and diet-related factors. Some aspects which may be established are:

- Drinking alcoholic beverages increases the risk of cancer of the oral cavity, pharynx, esophagus and larynx. A total 50%-70% of the mortality for these reasons can be attributed to alcohol.
- Drinking alcohol is also closely related to the risk of primary liver cancer, although the relationship be more difficult to prove in the epidemiological studies, given that most liver cancers linked to alcohol are subsequent to cirrhotic degeneration, which may have been induced, in turn, by alcoholism, this cirrhosis possibly having led an individual to reduce their alcohol intake.
- In epidemiological terms, drinking alcohol has also been linked to colorectal and breast cancer. Although the relationships are moderate and are debated, we are of the opinion that although the risk entailed in drinking alcohol may be minor, drinking may have some major public health-related implications (Robledo and Gil, 1998).
- The relative risk of such neoplasias increases 10-100 times over when smoking and drinking alcohol are combined (Boyle *et al.*, 2003). A relationship exists between the amount of intake (more than the type of beverage) and developing neoplasias, and also between the social class and the mortality due to cancer of these localizations.

Strategies for the prevention and fight against drinking-related problems

The current prevention strategies revolve around a population-based focus aimed at reducing the overall alcohol consumption (per capita consumption) and a high-risk focus targeting excessive drinkers, these two strategies being complementary, as is included under the European Alcohol Action Plans. Due to its multi-causal origins, with widely-varied consequences affecting different population groups, it must be said that no one single starring action exists for approaching this problem, but rather that all intervention strategies are encompassed within a more overall, comprehensive, multi-sectorial strategy, as is stated in the “European Charter on Alcohol”. Reducing the supply and demand for alcoholic beverages continues to be the cornerstone of the main preventive measures carried out through the Central and Autonomous Community Governments.

Lastly, as European reference points, special mention must be made, due to their importance, of the second European Alcohol Action Plan 2000-2005 of the WHO Regional Office for Europe, the Council recommendation on Alcohol Consumption on the part of young people, particularly younger children and adolescents of June 5, 2001 and the European Code Against Cancer.

Situation in Spain

According to the 2001 National Health Survey, more than 52% of the Spanish population ages 16 and above report regularly drinking some amount of alcohol within the two weeks immediately prior to the survey, it being important to stress that from 1987, when the first National Health Survey was conducted, up to 2001, the percentage of non-drinkers in Spain rose from 30.7% in 1987 to 37% in 2001, which corroborates the fact of there having been a reduction in alcoholic beverage consumption in Spain over the last twenty years, just as has occurred in other southern European countries.

The alcohol use and abuse phenomenon on the part of the *juvenile population* has currently taken on major dimensions in our society. The importance of this matter is due mainly to the *change in youth drinking pattern*. According to the last survey conducted on school-age children within the 14-18 age range by the National Drug Plan in 2002, alcohol continues to be the substance most consumed among youths 14-18

years of age. A total of 39.7% of the youths surveyed reported having gotten drunk at some time, 20.6% having done so within the last thirty days. Despite this, solely 7.4% feel they are drinking a lot or quite a bit of alcohol (National Drug Plan, 2003).

Environmental factors

This heading groups together a number of agents of differing degrees of far-reaching importance in their relationship to cancer and type of exposure (occupational, environmental, and iatrogenic) but which have a number of characteristics in common:

- They are of recognized major importance despite the piecemeal knowledge thereof as regards both their mechanisms of action and interrelationships as epidemiological factors.
- The methodology employed in the studies of these factors involves specific problems making it more highly complex. For example, an environmental pollutant may be harmful once included in the diet (dioxins) or mediated by means of a hormonal stimulus (endocrine disruptors).
- These agents sometimes increase the incidence of tumors considered as being emerging tumors (melanoma, germinal tumors, leukemias and lymphomas or brain tumors) with a greater incidence among younger-aged individuals.
- Except regarding exposure to the sun, undoubtedly the factor of the most well-known, preventable repercussions, the control over its incidence in the cancer-causing process requires legislative and regulatory actions more than changes in individual human behavior, the coordination among different instances and administrations generally being required.
- In designing these standards and laws, adopting the precautionary principle seems preeminent over the risk principle.

Environmental control strategies. Situation in Spain.

Growing social concern has made the environmental problem into a strong argument in favor of developing an extensive European regulation, which has been set out recently in a European Environment and Health Strategy (SCALE Initiative) with the aim of “developing a Community system which will integrate all of the information on the status of the environment, the ecosystem and human health” (COM, 2003).

The occupational-type contamination (evaluated in the CAREX project within the Europe Against Cancer Program (Kauppinen, 1998) more often found to exist in our environment is due to the sun’s rays, second-hand tobacco smoke and silica (Maqueda-Blasco, 1998) for which specific prevention regulations are now in place.

Solar radiation and exposure to ultraviolet rays have merited special consideration, given their relationship to developing skin tumors and our special geographical location. In addition thereto, the frequency of skin tumors (melanomas and non-melanomas) has doubled over the past ten years in all EU countries, related to the increased exposure to the sun. Squamous cell tumors are closely related to the cumulative effect of prolonged exposures, being more frequent among people who work out in the sun. Basal cell tumors and melanomas are related more to intermittent exposures and a history of repeated sunburns. From the European Code proper, the different administrations and scientific societies have set out strategies for disseminating the preventive measures aimed at reducing total exposure time - particularly in young children-as well as the use of sunscreens.

The cancer-causing potential of some viruses has been known since the first part of the century. Some viruses for which substantial evidence of a cause-effect relationship has been found are: HTLV-1 (adult T9-cell leukemia), HBV, HCV (liver cancer), Epstein-Barr virus (Burkitt’s lymphoma, Hodgkin’s lymphomas, and nasopharyngeal cancer) and papillomavirus (types 16/18 being those most related to cervical cancer). In our environment, the hepatitis B vaccine is included in the childhood vaccine schedule, which covers more than 95% of the population.

The percentage attributable to the hepatitis B virus totals 20% of all liver cancers (60% attributable to HCV) (Bosch, 2000). Lastly, some regions of Spain where intensive of agriculture is highly-developed are of special interest in the toxicological and healthcare study of contamination by chemical agents and endocrine disruptors (Olea *et al.*, 2002).

The Europe Against Cancer Program (EC 96/646) and the subsequent expansions thereon is a good driving force for the cancer control initiatives, specifically for the primary prevention strategies to meet with the merited dissemination and consideration. The European Code Against Cancer, which has recently been revised (Boyle *et al.*, 2003), includes the best-documented recommendations at this time concerning primary prevention and must continue being a reference point for all those strategies which are designed from the different Cancer Strategies.

EUROPEAN CODE AGAINST CANCER RECOMMENDATIONS IN PRIMARY PREVENTION

If you adopt a healthy lifestyle, you can prevent certain types of cancer and improve your overall health:

- **Do not smoke. If you do smoke, quit as soon as possible. If you cannot quit smoking, never smoke in the presence of non-smokers.**
- **Avoid obesity.**
- **Do some moderate physical activity every day.**

Increase the amount of fruits, green leafy vegetables and varied garden produce you eat: eat at least five servings per day. Limit your intake of foods containing animal fats.

If you drink alcohol - whether it be wine, beer or hard liquor - moderate the amount to a maximum of two drinks or units daily if you are a male, and to one if you are a female.

Avoid overexposure to the sun. It is especially important to safeguard children and adolescents. Those persons who have a tendency to get sunburns must shield themselves from the sun on a lifelong basis.

Strictly enforce the legislation intended to prevent any exposure to all possible cancer-causing substances. Fully comply with all of the health and safety recommendations concerning the use of these substances. Enforce the radiological protection standards.

Most of the actions dealt with hereinabove, as well as those to be reviewed in following have a bearing not only on regulatory and public health measures, but also on changes in individual habits. In all of these strategies, it is necessary to have proper coordination with the media. The necessary efforts must be made so that the measures and recommendations will reach all citizens by means of clear, pertinent messages through the media.

3.1.2 Standard

Reduce the prevalence of risk factors and the incidence of cancer by means of adopting health promotion and protection and cancer prevention measures.

3.1.3 Objectives

Smoking*

Reduce the prevalence of smoking among the population:

- By 2007, reduce the prevalence in the adult population (>15 years of age) to 28% (males 35%, females 25%).
- By 2007, reduce the prevalence among young people (16-24 years of age) to below 36%.
- By 2007, the percentage of ex-smokers should be above 23%.

* According to the objectives proposed in the National Smoking Habit Prevention and Control Plan.

Obesity

By 2007, reduce the prevalence of obesity to 11% in males and females.

Diet

By 2007, increase to 60% or more the percentage of the population which eats five or more servings of fruits, green leafy vegetables and produce in their daily diet.

By 2007, reduce to 36% the calorie intake in fats, mainly from saturated fatty acids.

Drinking

By 2007, reduce the intake of alcohol in the population within the 25-60 age range by 3% and by 5% among the population within the 18-24 age range.

Physical activity

Socially standardize the practice of physical activity entailing a benefit for health.

By 2007, increase the average number of calories used up in physical activity to 2,000 kcal/week in the population within the 10-24 age range and to 1,900 kcal/week among the population within the 25-74 age range.

By 2007, increase the percentage of the population within the 10-24 age range which are involved in physical leisure-time sports activities to 50% and to 30% among the population within the 25-74 age range.

Environmental factors

By 2007, quantify the environmental exposure to hazardous chemical preparations and substances classified as carcinogenic.

By 2007, reduce the levels of exposure to UV rays and artificial radiation on the part of the population.

3.1.4 Critical points

Smoking and drinking

- Insufficient impact and penetration of the smoking and drinking prevention actions, especially when the example-setting effect of healthcare professionals, parents and teachers, as well as that of the society at large, is not the most appropriate.
- Smoking and drinking is still part of the accepted “social norm”.
- There are pressures from the tobacco and alcoholic beverage industries to maintain their economic interests.
- The taxability to enforce on tobacco products and alcohol entails more of a tax-collecting aspect than a smoking and drinking dissuasion aspect, which could change if the taxes were to be allocated, in full or in part, to the Cohesion Fund to be earmarked in the end for the Integral Cancer and Ischemic Cardiopathy Plans.

Diet, obesity and physical activity

- Limited number of professionals with training in nutrition and dietetics capable of furnishing dietetic counseling in primary health care and who are available to take part in health promotion activities which involve changing eating habits and fostering a non-sedentary lifestyle.
- Limited budgeting allocated to health promotion activities by way of encouraging healthy eating habits and fostering physical activity.
- Insufficient heightening of awareness, information and training of the population in order to be able to configure healthy eating habits. The healthy eating option

is not the most affordable or the easiest alternative in many everyday situations: school, work, group lunchroom environment.

- Insufficient heightening of awareness and training of the healthcare professionals concerning the impact of eating habits on health and in the strategies for the modification of health-related behaviors.

Dissemination of the European Code Against Cancer

- Very little information on the different risk factors related to developing cancer.
- Insufficient heightening of awareness on the part of the population, those in charge of healthcare and healthcare professionals as to the need of adopting healthy lifestyles capable of having a bearing on reducing the incidence of cancer.
- Deep-rooted “It’s not going to happen to me” misconception among the population with regard to cancer.
- Prevalence of the disease-centered healthcare model on the part of certain sectors of the healthcare professionals.

3.1.5 Actions

Smoking

General and legal scope

- Implementation of the National Smoking Habit Prevention and Control Plan, by allocating the necessary resources to this Plan in order for it to actually be carried out.
- Adopting of the European Union directives and recommendations concerning smoking habit prevention and control.

- Ratifying and fully undertaking the World Health Organization Framework Convention for Smoking Habit Control.
- Assuring full compliance of the regulations in effect concerning tobacco product advertising, sponsorship, sale and use, including the penalizing activities.
- Foster the tax-related and legal measures for raising tobacco product prices and controlling contraband.

Health promotion education/training scope

- Increase the informing of the population as to the effects of active and passive exposure to tobacco smoke by means of general campaigns and specific campaigns by age, gender, social condition or other groups (ex. Pregnant women, small children, immigrants, etc.).
- Improve the training of “trendsetting groups” (physicians, nurses, pharmacists, teachers and professors) as to the health-related effects of smoking.
- Foster smoke-free public places and workplaces, especially healthcare buildings (healthcare centers and hospitals), school buildings (elementary schools, high schools, universities) and Government buildings in general.

Care scope

- Promote the detection of smoking and the practice of systematic anti-smoking counseling among the population for which care is provided in all fields of the health system.
- Train the healthcare professionals in the prevention and treatment of the smoking habit.
- Guarantee the overall dealing with and treatment of smoking dependency on the part of the National Health System.

Diet and obesity

- Prevent obesity and foster a healthy eating pattern.
- Favor health and consumer education strategies among the population at large which disseminate clear, simple information by way of different channels.
- Set out the measures necessary to make the training and skill development of the teaching personnel possible in order to implement nutrition education activities and foster physical activity within the school environment.
- Support initiatives aimed at designing and evaluating the effectiveness of nutrition education programs in the school environment, the healthcare system and the population at large.
- Adopt the necessary measure which will definitively back the widespread implementation of nutrition education within the school environment.
- Favor nutrition education and physical activity-fostering strategies within the scope of primary health care as part of the health prevention and promotion activities.
- Regulate the qualitative make-up of the food offered in group lunchrooms, especially within the framework of school, workplace and institutional lunchrooms both of a public and private type so that it will be in keeping not only with sufficient but also healthy eating.
- Set out the measure making early detection of inappropriate eating habits which favor obesity and other health risks possible by means of the use of valid, simple, readily-useable tools.
- Adopt the necessary measures for favoring putting the proper labeling of food products into practice which will allow the consumer to identify the nutritional characteristics of products.

Physical activity

- Foster the practice of regular moderate physical activity among the population.
- Foster physical activity and sports activities suited to the age of the students being carried out at schools.
- Promote sports/physical activities being carried out as attractive alternative free and leisure time activities.
- Boost the integration of physical activity into everyday life by making the best use of everyday situations at the workplace, school, home, etc. (walking, taking the stairs...).

Drinking

- Ensure compliance with the regulations in force concerning advertising, sponsorship, sale and consumption of alcohol, including the penalizing activities.
- Foster, inform and educate the population at large and specific groups of the population (children, adolescents, pregnant women) as to the risks involved in drinking alcohol.
- Foster, among the young population, healthy alcohol-free leisure time activities.
- Heighten the awareness of the population concerning the need of moderating drinking.
- Carry out special interventions in specific groups (adolescents, smokers, etc.).
- Foster the intervention of the primary health care professionals regarding drinkers at risk (evaluation of consumption, provision of information and counseling).

Dissemination of the European Code Against Cancer (ECAC)

- Favor the implementation of the 2003-2007 Integral Plan Against Cancer.
- Promote dissemination campaigns of each one of the ECAC points, such as the World No Tobacco Day (May 31st) or the Europe Against Cancer Week (second week in October).
- Increase the informing of the healthcare professionals with regard to the actions recommended under the National Plan Against Cancer for each one of the ECAC points.
- Get the healthcare professionals (primary care, specialized care, pharmacies) involved in disseminating the ECAC recommendations through providing health advice.
- Train the professionals in field of education in knowledge concerning the ECAC points and get them involved in disseminating the same by adding these points into the health education topics for study, especially those related to smoking, drinking, eating and physical activity.

Environmental exposure

- Staunch support of European initiatives concerning reducing exposure.
- Setting up a system for measuring, recording and monitoring exposure.

3.1.6 Examples of good practices

SMOKE-FREE HOSPITALS CATALONIAN SMOKE-FREE HOSPITAL NETWORK

The project was configured as a concerted institutional action among the different professionals and groups of the institution, combining the explicit, public commitment of the management team and of the union leaders with the active involvement of the professionals. The characteristics of this model are: 1) what is referred to as “leadership visibility”, where the members of the management team, the union leaders and the professionals play an exemplary role independently of their status as smokers or non-smokers 2) the participation of all of the departments and services by means of setting up a Promoting Committee 3) the dissemination of the progress and phases of the project among the employees 4) lastly, by way of the evaluation of the process and of the results by means of conducting evaluations as to the respect of the smoke-free spaces and annually conducting prevalence and opinion surveys on the evolution of the project.

The Catalan Smoke-free Hospital Network was created in 2000 on the initiative of the Catalan Cancer Institute . In July 2003, 42 of the 66 (63.6%) hospitals for public use in Catalonia pertained to this network. The member hospitals undertook to adopt the integral “Smoke-free Hospital” model, to publish the signposting and informative material bearing the network corporate image and to conduct the periodical evaluations.

In October 2003, 42 of the 66 hospitals for public use in Catalonia were adhered to the network, with different degrees of implementation of the program (18 are now completely smoke-free hospitals, all of the others being in the starting stages: setting up a promoting group, situation analysis, etc.). Organizationally networking favors and further strengthens the sharing of experiences in real time, mutual supports regarding educations, training and evaluation tools and affords the possibility of carrying out common continued training.

SMOKE-FREE SECONDARY EDUCATION AUTONOMOUS COMMUNITY OF ANDALUSIA

This is a smoking habit prevention and promotion program carried out from an intersectorial perspective which was gotten under way in the Autonomous Community of Andalusia during the 2001-2002 school year. The objective is to create an impact through educating concerning the smoking habit during the adolescent years, where major changes take place at the personal level, concerning behaviors and relationships, hence first-year secondary school students having been chosen for carrying out this program.

Around 70,000 first-year secondary school students and 2,200 teachers from 1,000 Andalusian schools have guaranteed the scheduling of smoking-related education of at least 8 hours in length, which, due to its widespread, systematic nature, has marked a reference point for the State as a whole.

In 2003, a total of 645 schools, 1,154 teachers, tutors or guidance counselors, around 35,000 students and the centers participating in the “Smoke-free Secondary Education” program were spread out among 356 municipalities in eight Andalusian provinces.

At the end of the school year, an evaluation of the program summarizing the developments thereof is collected. Those classrooms which turn in the evaluation participate in a drawing for eight prizes (one per province) consisting of a week-long trip for the students taking part in the program.

"PRO CHILDREN" PROJECT AT SCHOOLS

A European multi-center project with the objective of encouraging young boys/girls to eat more fruit and green leafy vegetables by means of educational activities which are attractive and even fun, which foster active learning and reflection. This project starts off by helping the children understand the reasoning behind the program's main message "Eating sufficient amounts of fruit and green leafy vegetables is good for your health". The program then goes on to favor heightening the children's awareness by helping them to develop the skills necessary for recognizing what "sufficient amounts of fruit and green leafy vegetables" means (heightening awareness and increasing knowledge) and for them to also be capable of evaluating their actual situation with regard to fruits and green leafy vegetables, to analyze their own individual situation and the social context. As of this point, the following steps are aimed at encouraging the children to discover different ways of enjoying eating fruits and green leafy vegetables in order for it to be possible to go by the message's recommendations: develop skills, attitudes and behaviors. In the final stage, they will try to set out their own personal objectives in related to fruit and green leafy vegetables and to analyze whether or not they managed to meet these objectives, making decisions and taking on responsibilities within a real-life context. Specific educational material has been prepared which includes worksheets for each student, a teacher's guide and a specific individualized personal counseling computer program. In Spain, this program has been evaluated by means of a randomized intervention study with 11 schools at which the intervention has been carried out and 11 control schools in Bilbao. In addition thereto, this program is being carried out on a coordinated basis in the Netherlands and in Norway.

THE HEALTH PROMOTION AND PREVENTIVE ACTIVITIES PROGRAM

The Spanish Family and Community Medicine Society created the Health Promotion and Preventive Activities Program in 1988 for the purpose of integrating the prevention and promotion activities into the care-providing practices in primary care offices. This program is structured into a minimum packet of recommendations for adults (detection and counseling regarding smoking and drinking, high blood pressure control) and the childhood population, in conjunction with a number of specific activities in relation to certain specific subprograms. The recommendations are based on reviews of the studies on the effectiveness of the interventions, take into account those of the different international institutions which work in the preventive field and are updated every two years. Different working groups comprised of primary care professionals from the public health sector are in charge of drafting the recommendations and the program's other working documents. These documents include guides on how to put the different activities into practice (i.e. there is a guide on preventive activities related to cancer and several on health education activities), as well as a distance course on health prevention and promotion. Decentralized one-day sessions and different training workshops are also held to be attended by professionals.

More than 640 healthcare centers throughout Spain which provide care for a population of over eight million individuals are currently signed up for this initiative. Signing up for the program is voluntary and can be done to differing degrees, starting from the minimum packet up to all of the proposed activities. Every two years, an evaluation is made of a sample of medical records of the centers included, and at least two studies have been conducted on the effectiveness of the interventions. Another initiative connected with the Health Promotion and Preventive Activities Program is the Smoke-free Week, which takes advantage of the World No Tobacco Day to promote the practice of smoking habit control activities carried out through the healthcare centers which entail a strong Community-related aspect.

Source: *www.papps.org*

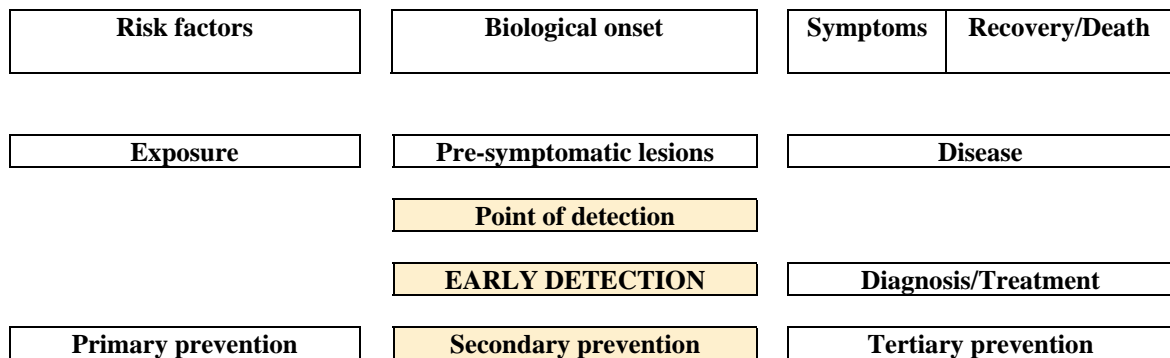
3.2 EARLY DETECTION

3.2.1 Background information

Screening principles

Any cancer prevention-related aspect is related to the study of its natural history, which is summarized in Fig. 3.1 below.

FIG. 3.1 NATURAL HISTORY AND PREVENTION LEVELS OF CANCER

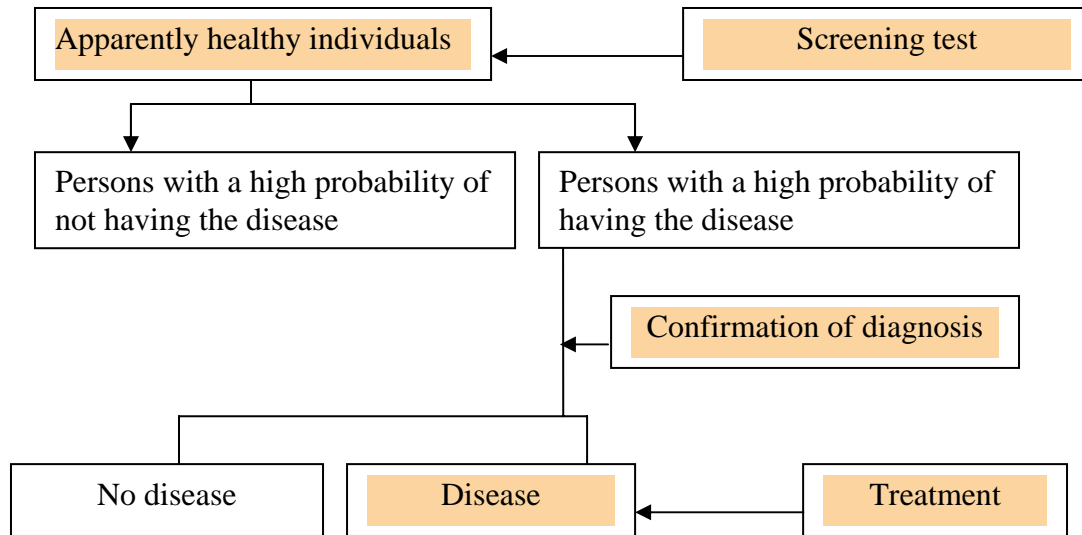


This diagram implicitly puts forth the notion of a disease evolving over the course of time and of the pathological changes possibly becoming irreversible over the course of time. Secondary prevention, implemented during the pre-clinical stage, is for the purpose of detecting the disease in its starting stage, in which the implementation of early treatment is more highly effective, thus halting further progress of the disease.

Disease control screening is defined as “the examination of asymptomatic individuals for the purpose of classifying them as having a high or low probability of having the disease for which the screening is being done” (Fig. 3.2). Those individuals

having a high probability of having the disease in question are examined in detail in order to come to a definitive diagnosis. Those in whom the disease is confirmed undergo treatment (Dos Santos, 1999).

FIG. 3.2 SCREENING PROCESS STEPS DIAGRAM



The screening is for the purpose of reducing the disease and mortalities resulting from the disease among the participating population. The success of a screening program when meeting this objective depends on the relationship between the characteristics of the screening procedures and the effectiveness of the early treatment method.

In order for a disease to be considered for screening, it must meet a number of requirements (Wilson, Junger, 1998).

- Be appropriate:
 - ✓ The disease must be of a sufficiently major magnitude so as to be considered a public health problem and promote a screening program.
 - ✓ The disease must include a preclinical stage in which it is detectable.

- ✓ The treatment employed during the preclinical stage must improve the prognosis in comparison to its being employed after the symptoms have developed.
- Make an appropriate screening test:
 - ✓ Which will be valid, stated by its sensitivity and specificity. The cutoff point making it possible to detect the maximum number of possible lesions (sensitivity) with the minimum number of false positives (specificity) must be found.
 - ✓ Which will be acceptable and cost. A screening test must be low-cost, acceptable, simple and must not cause any discomfort or complications.
- Have an appropriate screening program:
 - ✓ When the detection activities are carried out on the population by being applied to all of the subjects in a certain population, this is referred to as population-based screening, the series of procedures involved being referred to as a screening program. In such a case, it must meet a number of requirements which are summarized in Table 3.2 below.

TABLE 3.2 ESSENTIAL SCREENING PROGRAM ASPECTS

<ul style="list-style-type: none">• Proven effectiveness.• Clearly-defined target population with a possibility of identifying all of the individuals.• Sufficient resources to assure high coverage. Special emphasis is to be placed on recruiting more highly disadvantaged and/or less informed subgroups of the population.• Sufficient resources for carrying out the screening tests on the entire target population within the suggested intervals and guaranteeing continuity.• Accepted guides concerning the diagnostic and therapeutic procedures including the endowment of adequate resources for the implementation thereof.• Quality guarantee of the entire process, including the equipment used.• Introductory and continued training of the personnel.• Existence of an information system making continuous evaluation possible.
--

The idea that early diagnosis is always beneficial is deeply-rooted, however, in some cases it has no effect on the health of the person diagnosed. Mention should even be made of the fact that the process leading to the early diagnosis may sometimes even be detrimental to the individual, in which case the effect of the screening would be negative. Early treatment does not always improve the prognosis, but even if it does, the actual benefits of any type of screening must be evaluated by weighing them against the risks and costs involved in comparison to the benefits which may be derived from other public health activities (Table 3.3) (JARC. Breast Cancer Screening, 2002).

TABLE 3.3 SCREENING PROCESS BENEFITS AND ADVERSE EFFECTS

BENEFITS	ADVERSE EFFECTS
<ul style="list-style-type: none"> ● Better prognosis in some cases, which leads to: <ul style="list-style-type: none"> ✓ Preventing deaths. ✓ Gaining years of life. ● Less aggressive treatments, resulting in: <ul style="list-style-type: none"> ✓ Improving the quality of life. ✓ Cost savings. ● Peace of mind due to a negative result (in true negatives). 	<ul style="list-style-type: none"> ● Prolonged morbidity in cases without improved diagnosis. ● Unnecessary examinations and anxiety in false positives (added costs). ● Overtreating imprecise lesions with the resulting rise in cost. ● False peace of mind in false negatives, with loss of chance of early diagnosis. ● Medical risks of the examination.

Despite the potential disadvantages of early diagnosis, its true value must not be underestimated or overlooked. For this reason, the effectiveness of any screening program must be constantly controlled by implementing a coherent, coordinated, systematic focus. A quality assurance protocol is a key element in any screening program, given that it defines the standard which must be maintained in each one of the program components.

Early detection strategies

As previously stated, when the detection activities are carried out on all of the subjects in a given population, this is referred to as *population-based screening*. When groups of individuals are identified who have a significantly higher risk than the average for the population of developing the disease in question and the *screening* activity is targeted solely on these individuals, the *screening* strategy is termed *high-risk* (Martín, González, 1991).

Opportunistic (searching out cases) early detection includes those asymptomatic subjects who spontaneously request a screening test or are suggested to undergo screening by the healthcare service proper. In this case, more of an individual rather than a group benefit is sought, but this strategy must be evaluated with the same methodological seriousness as the population-based screening and must be prevented from being used as a substitute for population-based screening when there is not as yet any proven evidence as to the benefits thereof (Borrás *et al.*, 2003).

3.2.2 Standards

The entire populations shall have access to specific early detection programs and interventions in accordance with their own characteristics which will afford the possibility of reducing their risk of morbid-mortality in relation to those tumors for which the efficiency and effectiveness thereof have been proven.

No screening interventions of either an individual or population-based type shall be carried out if the efficiency thereof has not been scientifically proven.

3.2.3 Breast cancer

Background information

Despite certain controversies, the results of the case-control studies and clinical trials conducted to date are consistent. Based on the majority thereof, the conclusion is reached that performing periodical mammograms leads to reducing the risk of dying from breast cancer (Spanish Healthcare Technologies Evaluation Agency [AETS]: population-based breast cancer screening by mammogram, 1995) (Sankila *et al.*, 2000)

(Spanish Healthcare Technologies Evaluation Agency [AETS]: Evaluation Report No. 36, 2002) (IARC: Breast Cancer Screening, 2002) (Curry *et al.*, 2003) Jöns, 2003).

With regard to the effectiveness of screening among females under 50 years of age, the controversy continues concerning its efficiency with regard to achieving a significant reduction in the mortality for this age group (Kerlikowske *et al.*, 1995) (Humphrey *et al.*, 2002).

Where a general consensus does exist is with regard to the recommendation of implementing breast cancer screening programs of a population-based type among all women within the 50-69 age range (Canadian Task Force on Preventive Health Care, 2002) (US Preventive Services Task Force, 2002) (National Health Service, 2002) (European Communities Commission, 2003) (Cierco, 2003) (Boyle, 2003. European Code Against Cancer).

Regarding the screening tests studied, a majority agreement exists as to using the mammogram as the sole test. Combining the mammogram with a physical examination, although possibly increasing the sensitivity of the process, does not achieve a greater reduction in the mortality.

As regards breast self-exams, there is reasonable evidence of their being of no benefit and good evidence of harm, their being performed therefore must not be recommended (Baxter, 2001).

The third edition of the “European guidelines for quality assurance in mammography”, published in 2001, set out the recommendations and standards to be achieved in the different aspects comprising a breast cancer screening program (mammography technique, radiographic and radiological aspects, pathological anatomy, surgical treatment, evaluation and training) (Perry *et al.*, 2001) in order for it to truly be effective and achieve a significant decrease in the mortality.

Special mention must be made of the genetic factors related to this disease (Spanish Healthcare Technologies Evaluation Agency [AETS]: Evaluation Report No. 32, 2002). It is calculated that 5%-10% of all breast cancers are hereditary, up to 15% being hereditary among women under 45 years of age. The genes which are currently associated with syndromes of genetic predisposition to breast cancer are BRCA1 and BRCA2, although it is suspected that there must be others as yet unidentified. The detection or suspicion of existing alterations in these genes makes it possible to identify women who are carriers of a mutation with a predisposition to having breast and/or

ovarian cancer, and also of individuals at risk which could benefit from specific preventive surveillance or therapeutic strategies. However, only if a pathological mutation in the family is detected should the analysis be conducted on other members (Ruano, 2002).

Objectives

- Guarantee the existence of organized population-based screening programs, the bases of which are established as follows:
 - ✓ Target population: All women within the 50-69 age range.
 - ✓ Screening test: mammogram.
 - ✓ Length of time between examinations: 2 years.
- Guarantee a specific, individualized follow-up of those women who have a personal record of in situ lobular carcinoma or atypical epithelial hyperplasia.
- Guarantee access to specialized multidisciplinary departments where the individual and family risk will be evaluated, including the indication of performing a genetic study and counseling on women at high risk of having this tumor (hereditary risk):
 - ✓ Families with three or more direct family members (at least one first-degree relative of the other two) affected by breast and/or ovarian cancer.
 - ✓ Families with less than three family members affected by breast and/or ovarian cancer, which also fulfill some of the following high-risk factors:
 - Breast cancer diagnosed prior to 30 years of age.
 - Bilateral breast cancer diagnosed prior to 40 years of age.
 - Breast and ovarian cancer in the same patient (synchronic or metachronic).

- Breast cancer in a male.
- Two cases of breast cancer diagnosed prior to 50 years of age.
- Two or more family members affected by ovarian cancer, independently of the age.
- A breast cancer and an ovarian cancer.
- A family member has a genetic mutation (BRCA1, BRCA2).

Critical points

- Lack of information both among healthcare professionals and among the population at large concerning the risk factors which truly have a significant bearing on the onset of this disease within our context, as well as the efficiency and effectiveness of the screening among young women.
- Great sociosanitary pressure for screening mammograms being taken on young women. Many mammograms are currently being performed on asymptomatic women outside of the organized programs without their pertaining to high-risk groups. In most cases, the impact thereof and whether they fully meet the required standards of quality is unknown.
- Not all of the screening programs are meeting the required standards for achieving the potential reduction in the mortality (participation, detection rate, etc.).
- Territorial inequity with regard to the existence of specialized departments affording the possibility of integral treatment (information, study and follow-up) of women at high risk.

Actions

All of the Autonomous Communities shall guarantee coverage, within the shortest length of time possible, by organized population-based screening programs of 100% of the target population.

The population-based screening programs shall follow the recommendations of the European Mammography Quality Control Guides. All of the requirements of a population-based screening program (Table 3.1) shall be fully met, specifically:

- A recruiting system shall be developed which will make it possible to achieve at least a 70% participation rate.
- Women shall be furnished with sufficient information on the characteristics of the program, including the mammogram, on the validity and risks and benefits involved in the process so as to be able to make an informed decision as to their participation therein.
- An image quality control system shall be developed which will make it possible to obtain mammograms of sufficient quality to detect the maximum number possible of minimal tumors with the least number of false positives and with the minimum dose of radiation possible.
- A specific continued training process in screening mammography shall be guaranteed for all of the professionals involved, special emphasis being placed on radiologists and X-ray technicians.
- A complete follow-up on the cases detected must be assured. The referral circuits and study of the positive screening cases shall be clearly defined in order to guarantee the confirmation, diagnosis and treatment process within the shortest length of time possible.
- The reference centers for the diagnosis and treatment shall avail of the sufficient resources to guarantee the confirmation of the diagnosis and integrated treatment of the patient with guaranteed top quality.
- All of the programs shall avail, from the start, of an information system making the daily management, quality control and periodical evaluation possible. This system must make it possible to identify the women in the target population and to set up appointments for them, to make a record of the women's participation as well as of the results of the mammograms, to monitor the diagnosis process and to evaluate the program process management and results indicators. This information system must be safe and reliable and must guarantee the confidentiality of the data involved.

- Total quality guarantee programs shall be implemented which will take in all of the program phases.
- The Ministry of Health and Consumer Affairs, in collaboration with the Autonomous Community Health Councils, shall carry out informative actions which shall allow both healthcare professionals as well as women in general to know the risk factors related to this tumor and the risk-benefit of mammograms being taken on asymptomatic women outside of the target age group of the population-based screening programs.
- The mammograms which are taken on asymptomatic women outside of the target age range of the population-based programs shall be subject to the same quality control which are required for the target age range following the recommendations of the European Mammography Quality Control Guide.
- The Health Services of the different Autonomous Communities shall promote the creation of multidisciplinary departments specialized in “cancer genetic counseling” which shall assess the individual and family risk of those women subject to having a hereditary cancer syndrome.
- The different care levels shall actively recruit these high-risk women and shall refer them to these departments, where the specific screening guideline shall be determined in terms of their risk.
- The Autonomous Community populations screening programs which include the group of women within the 45-49 age range as the target population shall specifically evaluate the process results and the impact of the program on this age groups.
- The evaluation agencies shall periodically analyze the new evidence regarding the effectiveness of the screening in other age groups (ages 40-50) for the purpose of modifying the recommendations for coverage of these age groups at the point in time when the conclusion is reached as to evidence existing.
- The evaluation agencies and/or groups of experts set up for this purpose, shall prepare reports in relation to the following subjects:

- ✓ Attitude toward women undergoing hormone replacement treatment.
- ✓ Attitude toward women with breast prosthesis implants.
- ✓ Follow-up of women at high risk.

Examples of good practices

NAVARRA EARLY BREAST CANCER DETECTION PROGRAM

The Breast Cancer Prevention Program was started, for purposes of performing mammograms, on March 3, 1990. This Program includes all of the women within the 45-69 age range (ages 45-65 up to 1998) residing in Navarra as the target population. All of the women who come in for the first time are given two mammograms (as of the third round), those who have previously been examined being given only one.

An overall 86.86% participation is being achieved in all. A total of 89.39% of the women notified have come in at least once. A total of 96.28% of the women have repeated the examination within the set timeframe (2 years). The overall detection rate is of 3.98 /1000.

Comparing the tumors which have been diagnosed through this program within the 1990-1998 period with those which have been diagnosed by other means, a clear difference has been found in favor of the former, both in size as well as in the percentage of tumors with ganglionar invasion.

The five-year relative survival rate for breast cancer in Navarra has risen from 71.2 in the tumors diagnosed for the 1985-1989 five-years period to 82.0 for the 1990-1994 five-year period (15.17% increase), with a significantly higher rise among the 45-65 age group. For the tumors detected by the program, the five-year relative survival rate is 93.3%.

Regarding the mortality resulting from this tumor, a reduction in the risk of death has been observed as of the 1993-1995 three-year period. The decrease in the risk assigned by the model (age-period-cohort analysis) for this purpose is important, around 40% for 1993-1995 and 1999-2000, with an approximate 7% annual decrease.

Source: Navarra Public Health Institute. 2003 Early Breast Cancer Detection Program.

**GENETIC COUNSELLING DEPARTMENT MODEL.
CATALONIAN ONCOLOGY INSTITUTE. BARCELONA.**

The Genetic Counseling Department of the Catalanian Oncology Institute was gotten under way in November 1998. To date, a total of 650 families with a suspicion of hereditary breast or ovarian cancer have been seen. In all cases, the personal and family risk of these cancers have been estimated, and the primary and secondary prevention guidelines in accordance with the estimated risk have been indicated. A total of 292 of the families met hereditary breast/ovarian cancer criteria, the study of the germ-line BRCA1 and BRCA2 genes being suggested. Deleterious mutations have been detected in 28% of the families studied. The identification of a deleterious mutation responsible for hereditary susceptibility to breast and/or ovarian cancer makes it possible to more accurately evaluate the personal risk of developing breast or ovarian cancer.

Source: www.iconcology.catsalut.net/duran+i+reynals/atencion+al+usuario/consejo.htm

**GENETIC COUNSELLING DEPARTMENT MODEL.
MEDICAL ONCOLOGY SERVICE. HOSPITAL CLINICO SAN CARLOS. MADRID**

The Counseling Department is comprised of three areas: the care-providing area, the molecular oncology laboratory and the hereditary syndrome registry. The professionals comprising this Department come from different healthcare fields: oncologists, nurses, psychologists, pharmacologists, biologists, biochemists. In addition to these professionals routinely imbricated into the genetic counseling, the care-providing program is rounded out with out specialists in relation to the different cases which come in for consultation: gynecologists, surgeons, pathologists, endocrinologists, pediatricians, geneticists, radiologists, etc.

The prime objectives of this Department are clinical care (genetic counseling) and research (basic, translational and clinical). Within this first objective, genetic counseling could be defined as the process by which we inform the persons who come in to our office as to the possibilities of having cancer, the possibilities of transmitting it and the possibilities of medically and psychologically handling this situation.

Within the genetic counseling process, it may be useful and necessary to perform a genetic test, which may afford us with the possibility of detecting a person who carries a mutation of a predisposition gene for cancer, which would involve some major consequences both for the person per se and for their family members in the handling of this risk. The center performs determinations for the BRCA1 and BRCA2 susceptibility genes and MMR genes (responsible for the non-polyposic hereditary colon cancer syndrome).

3.2.4 Cervical cancer

Background information

The effectiveness of cervical cancer screening has never been studied by means of random clinical trials. However, the case-control, cohort studies and the analysis of trends and different geographical locations have shown a cervical cytology (Pap Test) performed every 3-5 years to be effective for reducing the incidence and mortality resulting from this tumor (Boyle *et al.*, 2003-European Code Against Cancer) (Avalia-t: Cervical cancer screening, 2002) (Sankila *et al.*, 2003).

According to the studies conducted in countries having incidence rates similar to those of Spain, the protection period following a cytology with a true negative result would total up to ten (10) years, which would provide some leeway with regard to setting a recommended five-year and never less than three-year interval between tests (Viikki *et al.*, 1999) (Sawaya *et al.*, 2003).

Most of the recommendations concerning the recommendable age for beginning to implement the screening tests are based on studies of lesion prevalence at different ages and on the relationship between sexual activity and cervical cancer, there thus being a tendency toward recommending early starting ages coinciding with the start of sexual relations. However, based on the protection conferred by the screening test if there is a true negative, the maximum performance would seemingly be achieved by starting 5-10 years prior to the maximum age of incidence (25-35 years) and continue up to 55-60 years of age (Avalia-t: Cervical cancer screening, 2002).

A widespread consensus also exists in this case for recommending the starting up of population-based screening program (Canadian Task Force on Preventive Health Care, 2002) (National Health Service, 2003) (European Community Commission, 2003) (Boyle *et al.*, 2003-European Code Against Cancer) (Curry *et al.*, 2003), although the magnitude of this health problem is quite low at this point in time in Spain (very low incidence of cancer and low prevalence of human papilloma virus infection). The impact of the screening on this type of populations is unknown, but from an individual standpoint, it would afford the possibility of detecting precursor lesions and the early detection of the cancer proper, provided that some minimum standards of quality were fulfilled.

In this regard, just as in the case of breast cancer, European guides having been published including the recommendations which any cervical cancer screening program must fulfill (Coleman, 1993).

Liquid-phase cytology could mean a significant advance over the conventional Papanicolaou technique, given its greater representativeness in the sample analyzed, the possibility of automating the reading thereof, the major reduction of ambiguous results and the higher sensitivity for high-degree lesions. Viral testing has also been evaluated as a primary screening test, with the cytology or biopsy as a secondary test to confirm the lesion. The International Cancer Research Agency evaluated the evidence published up to February 2004 on cervical cancer screening, having come to the conclusion that both liquid-phase cytology and the automated reading of the slide and the HPV DNA detection are each proper techniques for primary screening of a minimum performance as satisfactory as conventional cytology (IARC Monograph, 2005).

The development of prophylactic, therapeutic or combined vaccines is a new option for the prevention or treatment of HPV infections and perhaps for the treatment of the established infections. The future cervical cancer protocols may go so far as to change the current paradigm, probably including the HPV vaccine with polyvalent preparations in adolescents, following by a more further-spaced screening combining viral detection with conventional or liquid-phase cytology (IARC Monograph, 2005).

Objectives

- Guarantee that a specific follow-up be carried out in organized programs for women at high risk, defined as being women who come from countries having a high incidence of this disease and/or susceptible to a related disease (HIV or other sexually-transmitted diseases).
- Optimize the resources employed in performing opportunistic cytologies.
- Guarantee that the cytologies performed on women who are not high-risk fulfill the following criteria:

- ✓ Target population: asymptomatic women which are currently or have been sexually active who fall within the 25-60 age range.
- ✓ Screening test: cervical cytology.
- ✓ Interval between examinations: when coming in for the first time, two cytologies shall be performed within a one-year period. In case of negative results, the recommended time interval shall be 3 years in women within the 25-39 age range, being possible to extend to 5 years for women over 40 years of age.
- Guarantee that at least 80% of the women within the 40-50 age range have had a cytology performed within the past 5 years.

Critical points

- The lack of information among both healthcare professionals and the women themselves regarding the frequency and risk factors conditioning the onset of this disease and, in short, regarding the need and benefit of screening.
- A very large number of cytologies are currently being performed in Spain and often very frequently, spaced one year apart, which gives rise to a major use of unnecessary resources.
- Accessibility to cytology differs greatly. The equity criteria requirable of a healthcare program are not being met. Self-selection exists when accessing having a cytology performed, biased in the sense of a lesser participation on the part of social groups at higher risk and lower socioeconomic conditions.
- The poor quality in a large percentage of samples (incorrect sample taking), which invalidates its reading and makes a correct diagnosis impossible, with the resulting loss of efficiency.

Actions

- The Ministry of Health and Consumer Affairs, in collaboration with the Autonomous Community Health Councils, shall carry out information campaigns targeting both healthcare professionals and the population at large concerning the incidence of this disease, the individual risks of be stricken with this disease and dying for this reason, the risk factors involved and the recommendations to be followed.
- Although cytologies are not performed within the framework of an organized population program, they shall be subject to the quality control recommendations required of a population-based program. The entire activity shall be organized following the recommendations of the European Quality Control Guides.
- All of the cytology reports shall be made in a protocolized manner in accordance with the recommendations of the scientific societies involved.
- An exhaustive study shall be made of the screening cytologies offer, analyzing the type of population to which it is applied, its periodicity, the results thereof and the costs entailed, for the purpose of being able to evaluate the overall impact thereof.
- The healthcare centers, gynecology offices and women's care centers shall identify and recruit the high-risk population groups having less accessibility to the healthcare system. Special emphasis shall be placed on getting sexually active women who have had no prior cytologies to come in for testing.
- Close epidemiological surveillance shall be maintained by means of conducting periodical population-based surveys on the prevalence of the human papilloma virus for the purpose of detecting significant increase thereof and modifying the recommendations in relation to intervention strategies.
- An analysis shall be made as to the usefulness in our environment of the new methods developed, more specifically of the liquid-phase cytology, the automatic reading systems and the detection of DNA-HPV infection, as a screening test.

Example of good practice

ACTIVE SKILL DEVELOPMENT IN HIGH-RISK GROUPS AND COORDINATED, INTEGRATED ACTIONS. GALICIAN HEALTH COUNCIL

An integral intervention for the prevention of prostitution has been being carried out since 1998 in the Autonomous Community of Galicia, the general objectives of which are to facilitate and promote social and health care to the group of women involved in prostitution in conjunction with the primary and secondary prevention of certain diseases (HBV, HCV, tuberculosis) and STD's (HIV, syphilis and cervical cancer).

This intervention is being carried out by *Alecrín*, a NGO working in the field of women and prostitution, in collaboration with the Galician Health Council. To facilitate recruiting this group, Alecrín has a *mobile unit* which is used to move around to the main cities in Galicia, where it sets up on a pre-set schedule in what are referred to as the “red-light districts”, also visiting the nightclubs. Alecrín also has *day centers*, where the women can be provided with information and counseling.

The procedure consists of making oneself known and encouraging contact with the existing sociosanitary networks. Similarly, informative material (pamphlets, leaflets) and preventive material (condoms) are given out to the women. Those women who accept this help are referred to reference primary care offices or to family guidance centers for their study and follow-up, some of which have specific programs, such as the “Novoa Santos” Family Guidance Center in Orense.

3.2.5 Colorectal cancer

Background information

To date, the clinical trials conducted on the effectiveness of colorectal screening by means of the test for occult blood in feces show the mortality due to this tumor to be decreasing. This decrease was consistent throughout the four controlled trials (Minnesota, Nottingham, Funen and Goteborg), varying by 15% to 33% (Sankila *et al.*, 2000) (Avalia-t: Evaluation of the efficiency and effectiveness of population-based colorectal cancer screening, 2003) (Walsh *et al.*, 2003).

Based on the evidence found, the best strategy guaranteed, for the time being, for carrying out a population-based screening would be the test for occult blood in feces (Avalia-t: Evaluation of the efficiency and effectiveness of population-based colorectal cancer screening, 2003). The sensitivity of this test is however limited (not over 50%), and the positive predictive value is low (10%-18% for cancer diagnosis and 21%-38% for the diagnosis of adenomas larger than 10 mm). Additionally, the colonoscopy, the test for confirming diagnosis for the study of the positive cases, is a test entailing a certain degree of complexity requiring a large number of resources and entailing a risk of complications not to be slighted.

Other strategies, such as flexible sigmoidoscopy and the colonoscopy employed with different periodicities, are being evaluated as alternative screening methods (UK Flexible Sigmoidoscopy Screening Trial Investigators, 2002).

Different organizations are actively recommending this type of screening being gotten under way. The suitable age range would be 50-74 years of age, and the test for occult blood in feces would be used as the screening test on a biennial basis (Canadian Task Force on Preventive Health Care, 2002) (National Health Service, 2003) (European Community Commission, 2003) (Boyle *et al.*, 2003 – European Code Against Cancer).

However, a population-based colorectal cancer screening program is a complex project in need of evaluating studies concerning the suitability of its being gotten under way and, once this decision has been made, of a major organizational endeavor for its implementation.

One of the main problems involved in any screening program is getting the target population to participate, a high degree of acceptance being necessary in order to assure the benefit in terms of cost-effectiveness. The findings to date in clinical trials need not mean a guarantee of effectiveness of a certain population-based program if factors including that of a high degree of participation are not achieved, which does not seem highly possible to achieve in our environment for the time being.

It is however possible to identify individuals/families at risk of a hereditary colorectal cancer predisposition syndrome which may benefit from genetic counseling and from specific preventive, surveillance or therapeutic strategies.

Objectives

- Promote the conducting of pilot population-based screening studies using occult blood in feces affording the possibility of coming to a decision, within the shortest time frame possible, as to the best strategy to be implemented in a populations program.
- Guarantee the proper follow-up of those persons with adenomatous polyps considered high-risk or with inflammatory intestinal disease.
- Favor access to specialized multidisciplinary departments where the individual and family risk may be evaluated, including the indication of conducting a study and genetic counseling for those persons at risk of hereditary cancer (familial adenomatous polyposis, non-polyposic hereditary colorectal cancer, family history of colorectal cancer).

Critical points

- The test for occult blood in feces entails some limitations: its sensitivity is limited and the positive predictive value is low, which means that a large number of people must undergo tests for the purpose of confirming the diagnosis. Additionally, its acceptability is very low; the participation of the population is noticeably lower than for other cancer screening processes already in place, both for the initial test as well as for the follow-up tests (the pilot studies conducted to date at the population-based level have not met the minimum participation objective in order to achieve a reduction in the mortality).
- This screening test both has not met with good acceptance among the population and the healthcare professionals, despite its proven effectiveness, probably due, in addition to the characteristics of the screening test proper, to its benefits being perceived to only a very small degree and a lesser degree of social pressure.
- Colorectal cancer screening in high-risk population is very often not in keeping with the recommended indication, follow-up and evaluation criteria. A high degree of variability exists in the clinical indication of performing sigmoid/colonoscopies in individuals with low-risk diseases.

- No population registries exist of cases of diseases related to a high risk of cancer.

Actions

- Pilot studies shall be conducted in order to estimate the degree of acceptance and feasibility in our environment of a population-based screening test. It is recommended that this be carried out under a coordinated design scheme for the purpose of gleaning the maximum amount of information possible from them.
- An exhaustive evaluation shall be made of the different pilot projects, placing special emphasis on determining the recruiting method affording the possibility of achieving a maximum degree of participation and adherence in the way of implementing the screening test which will result in the minimum number possible of false positives.
- An evaluation shall be made of the material and personal resources necessary for the confirmation of the diagnosis and treatment of abnormalities detected which would require the implementation of a population-based screening process.
- In addition to the endowment of all of the necessary resources, it is considered fundamental, at the point in time at which a population-based program is going to be implemented, for general campaigns be carried out to heighten the awareness of both healthcare professionals and the population at large as to the advantages, benefits, risks and limitations of early detection for the control of this disease.
- The evaluation agencies shall periodically review the new evidence as to the effectiveness of the screening process by means of new methods, specifically the role of the sigmoidoscopy, colonoscopy and strategies employing combined methods.
- An exhaustive study shall be made of the current screening test offer, analyzing the type of populations to which it is applied, its periodicity, the results of the tests and the costs entailed.
- population-based registries of cases of diseases related to a high risk of cancer must be created.

- The health centers and digestive, surgery and oncology services shall identify and recruit the high-risk population groups. These individuals shall be offered an organized follow-up program which, as such, must meet all of the set requirements in order to achieve the maximum benefit with the least number of adverse effects.
- The Health Services of the different Autonomous Communities shall foster the setting up of departments specializing in cancer-related genetic counseling which can provide a response to individuals with a hereditary risk of having this tumor.

Examples of good practices

EARLY COLORECTAL CANCER DETECTION PILOT STUDY. CATALONIAN ONCOLOGY INSTITUTE

In 2000, the Catalan Health and Social Security Department started a pilot program for the early detection of colorectal cancer on a population-based basis offered for males and females within the 50-69 age range in the municipality of l'Hospitalet de Llobregat, with a target population of 64,357 individuals with the objective of determining the degree of acceptance and feasibility of a population-based screening program for this cancer in our environment.

The invitation to take part in the program is extended by way of letters addressed personally to each individual, the test for occult blood in feces being used as the screening test, and the positive cases being investigated by colonoscopy with unintubated anesthesia without admission to hospital.

An information system is available for making appointments, registering the participation, the results of the test and of the diagnostic test and to evaluate the program results. The information system is computerized, reliable and secure and guarantees the confidentiality of the data.

The participation totaled 17% in all, some major variations having been found to exist among basic health districts ranging from 10.3% to 26.7%. The screening test was positive in 3.4% of the participants. The detection rate per 1,000 individuals screened is 1.7 for invasive cancer, 4.2 for invasive and/or in situ cancer and 9 for invasive cancer and/or adenomas. The result show the screening strategy used to be viable, and some good results have been achieved in the detection of neoplastic lesions, although the participation is considered to be low in comparison to other screening processes. The second round has currently been started with the objective of evaluating the degree of acceptance among those individuals who have taken part and among those who have not taken part.

COLON CARCINOMA CARE PROCESS HOSPITAL MARINA ALTA. DENIA

Beginning as of 2002, a colon carcinoma care process has been being carried out at this hospital, including carrying out an organized screening program on a population group at moderate-to-high-risk of having this tumor.

The factors for considering a person as being at high risk are: a family history of familial adenomatous polyposis, Gardner's syndrome or Turcot's syndrome; a family history of non-polyposic colorectal cancer; inflammatory disease of an evolution of more than 8 years if of the ulcerous colitis type and of more than 15 years if of the Crohn's or segmental ulcerous colitis type. Based on these criteria, it is calculated that the target population would total approximately six percent (6%). The criteria for considering an individual to be at moderate risk (approx. 20% of the population) are also defined.

The recruiting was done through primary care or through other hospital consultations. "General information guides" and "informed consent pamphlets" have been prepared to inform those patients who are going to be referred to the program as to the entire process. The screening test employed is colonoscopy. There are clinical guides which specify the starting age and the frequency of use according to the risk or disease entailed. The therapeutic process and post-treatment follow-up is also protocolized. The indicators which are to be used in evaluating the program have been defined.

Source: Personal presentation. Ignacio López Benito.

THE MALLORCAN FAMILIAL ADENOMATOUS POLYPOSIS REGISTRY

The Mallorcan familial adenomatous polyposis registry includes the incidence and prevalence of the cases of this hereditary disease linked to colorectal cancer. A family from the island of Menorca is also control checked. This registry was begun in the early eighties and currently keeps a running check on some 28 families. The main objective of this registry is the prevention of colorectal cancer among the family members at risk. The family history is the main tool of the registry, given that it affords the possibility, as of the first case detected, of identifying the family members at risk of having this disease. Rectosigmoidoscopies are begun starting as of puberty. The possibility of studying the genetic mutations in collaboration with the Translational Laboratory at the Duran i Reynals Hospital in Barcelona has also been incorporated. Genetic counseling, family training, prevention of tumor formation in other localizations and the study of extraintestinal manifestations are also carried out.

Source: Personal presentation. Antoni Obrador.

3.2.6 Prostate cancer

For the time being, no studies are available proving the efficiency of the screening for this tumor. The screening by way of a digital rectal exam, transurethral echography or prostate-specific antigen test has not shown any reduction in the mortality. Two randomized clinical trials are currently under way: the European Randomized Study of Prostate Cancer (ERSPC) (Schröder, Gangma, 1997) (Vis *et al.*, 2000) and the PLCO (Prostate, Lung, Colon Ovrey) trial of the U.S. National Cancer Institute (Prorok *et al.*, 2000), but the results are being found difficult to assess.

The systematic use of the prostate-specific antigen test in asymptomatic males entails a great number of false positives and false negatives with the resulting side-effects caused thereby. Additionally, the decision of justifying a population-based screening is complicated on not availing of clinical trials which have evaluated the effectiveness of the prostate cancer treatment in localized lesions.

In conclusion, it is not recommended that any prostate cancer screening program be carried out either on a population-based or individual basis in asymptomatic males.

Nevertheless, the fact must be stressed that this test is currently being carried out progressively more often without any indication whatsoever, it therefore being recommended to inform the healthcare professionals and the population as to the current status of the scientific evidence in this regard.

3.2.7 Skin cancer

There are two types of skin cancer: melanoma, which is less common yet is the type causing more deaths; and non-melanomas, which include basal cell carcinomas and squamous-cell carcinoma. Over the past few years, the incidence of melanoma has discreetly increased, although the mortality due to this tumor is relatively low.

The effectiveness of skin cancer screening is uncertain. The different studies available entail biases involving the detection of those tumors which are not highly aggressive, the overdiagnosis of lesions which would never have progressed into cancer and the benefit among those individuals who are most concerned about their health

(Helfand M, Mahon SM, 2001). A clinical trial on the general population is currently under way (Aitken JG, Elwood JM, 2002) from which further information may be gleaned.

The effectiveness of the screening has indeed been shown to be effective in the high-risk population (white-skinned individuals who burn easily and tan little, a personal or family history of skin cancer, a history of prolonged, intense exposure to the sun and individuals with a larger than average number of nevus (more than 50). Similarly, a cost-effectiveness study has found this screening on the high-risk population to be as cost-effective as the screening of other cancers among the population in general (Freedberg KA, Geller, AC, 1999).

In conclusion, the systematic screening for skin cancer among is general population is not recommended, but the active search for individuals with risk factors is advised.

3.2.8 Lung, tracheal and bronchial cancer

For the time being, no scientific evidence exists to recommend systematic screening among symptomatic individuals.

Different lung cancer screening trials using a chest X-ray and/or sputum cytology have not shown in reduction in the cancer mortality.

Recently, it has been proven that performing a CT scan using a spiral scanner can diagnose lung cancer in high-risk asymptomatic individuals. Although the results of these trials suggest that CT scans may be considered at some point in the future as a screening test useful for the early detection of lung cancer, it is still as yet to be determined if this is going to involve a reduction in the mortality, the screening of this type of tumor therefore not being recommended.

3.2.9 Other screening interventions

Scientific evidence currently supports screening processes for breast, cervical and colorectal cancer. The screening tests which have shown themselves to be effective, as previously discussed on an individual basis in the preceding sections hereinabove are mammography for breast cancer, cervical cytology for cervical cancer and the occult blood in feces test for colorectal cancer.

Scientific evidence similarly supports certain screening interventions not being carried out (Boyle *et al.*, 2003). This is the case of:

- Vanilomandelic acid and homovalinic acid in urine for neuroblastoma.
- Chest X-ray for lung cancer.
- Breast self-exam for breast cancer.
- Testicle self-exam for testicular cancer.

For a certain number of other cancers, the benefits of screening is unknown, but there are a number of clinical trials under way. The results of these studies make it possible to consider or rule out the use of these interventions in our environment at some point in the future, but, for now, no screening activity in relation to these tumors is recommended. The interventions which are currently being studied are (Boyle *et al.*, 2003):

- The C125 tumor marker and/or echography for ovarian cancer.
- Spiral CT scan for lung cancer.
- Helicobacter pylory test and imaging exams for stomach cancer.
- Nevus exam for skin cancer.
- Oral exam for oropharyngeal cancer.

3.3 ADULT CARE

3.3.1 Background information

Treating cancer in adults usually requires implementing the following treatment strategies: surgery, chemotherapy, radiation therapy, hormone therapy and biological response modifiers. The developments in cancer research make it possible suppose that new treatments will be added, based on a better knowledge of the molecular biology of cancer (De Vita *et al.*, 2002). On the other hand, cancer diagnosis and treatment require the collaboration of many specialists and the different professionals involved in the treatments must take action in coordination with one another in order to achieve the maximum treatment effectiveness, which is probably one of the most important facts justifying the need of planning in cancer care.

The survival rate data obtained from the population-based cancer registries in our country are the best indicators of the clinical results achieved in our patients. The EUROCAR project affords the possibility of comparing the data from different European countries using the same analysis methodology (Coebergh *et al.*, 1998). The most recent data, published in 2003 within the framework of the EUROCARE III project, make it possible to say that the survival rate in adults with cancer on record in the Spanish registries is ranked in a medium-high position within the European context (Sant *et al.*, 2003). Thus, the relative five-year survival rate for all tumors in males was 44%, while the European average was 39.8%, the country with the highest survival rate having been Austria (55%), followed by Sweden (49.9%). In females, the percentage found in the Spanish registries was 57.4%, whilst the European average was 51.2%, the country having the highest rate having been France (58.9%), followed by Austria (58.2%) These results must be taken with all due precaution, due to the fact that the Spanish registries included in this study are not representative of the entire Spanish population. The survival rate obtained indicates that cancer care in Spain is above the European average, but that there is noticeable room for improvement in many tumors and in cancer as a whole, especially in organization and resource-related aspects for cancer treatment.

The manner in which cancer care has been carried out in Spain has been determined by the difficulty involved in articulating the new multidisciplinary concept of cancer care within the conventional organizational structure of the hospital care services because of the needs of the cancer patient diagnosis and treatment process.

Similarly, another aspect worthy of special mention is the different pace at which cancer care has developed among medical specialties, care resources and Autonomous Communities over the last twenty years, as has been set out in the different editions of the white book on oncology in Spain published by the Spanish Federation of Cancer Societies (FESEO) in 1998, 1994 and 2002.

In synthesis, the main problems detected may be listed as follows:

- Cancer care being provided broken up among the different hospital services and centers without any connection among the care levels involved in the cancer diagnosis, treatment and follow-up process. These problems of the relationship among care level may explain a major part of the delays in cancer diagnosis (Porta *et al.*, 2003).
- Territorial inequity among and within the Autonomous Communities in accessing the specialized resources necessary for providing quality cancer care.
- Total lack of a cancer care coordination-organization model among the hospitals providing different levels of care and within the hospitals proper. This has led to there being hospitals at which cancer treatment is provided through the care service where the diagnosis has been made or rather through the first care service on hospital admission.
- Remarkable variability in the clinical practice of cancer therapy among professionals, hospitals and territorial areas, which may result in differences in the clinical outcomes (Peris *et al.*, 2001).

- Significant waiting lists in different diagnostic and therapeutic procedures.
- Deficit of radiation therapy equipment which has given and is currently giving rise to significant waiting lists (Esco *et al.*, 2003), at certain time in certain territories which are not making it possible to administer this treatment within oncologically suitable timeframes.
- Deficit of healthcare professionals devoted specifically to cancer care, as well as the small number of oncology professionals.
- Lack of definition of specialization criteria in complex and/or infrequent procedures which might afford the possibility of achieving better therapeutic effectiveness.
- Territorial inequity in patient access to the new techniques and technologies, keys in the future development of cancer care, such a liver metastasis surgery or the organ conservation treatments.
- Highly limited resources devoted to psychosocial care.
- Care protocols and clinical guides scarcely developed and also being limited to specific treatments (i.e. chemotherapy in breast cancer) and not covering the full-range care-providing process (breast cancer diagnosis and treatment).
- Relationship between research and clinical practical limited to a major degree to the conducting of clinical trials.
- Highly insufficient evaluation of clinical outcomes of the diagnosis and therapeutic procedures, given that information on the care-providing process (i.e. timeframes between treatments) has been provided solely in some cases.
- Very little patient involvement in managing their own process. The informing and participation of patients and their family members in selecting the treatment alternatives are still as yet highly limited.

Mention must be made of the fact that some significant changes have taken place aimed at changing this situation over the past few years. Some of the most important advances made over the past ten years are:

- The effort made in investing in radiation therapy equipment, which, although still as yet insufficient, has meant significant advances due both to what they mean with regard to updating equipment as well as with regard to territorial equity (Esco *et al.*, 2003).
- The progressive spreading out of oncologists in intermediate-level and regional hospitals, thus improving accessibility.
- The hesitant yet significant deeper delving into clinical and preclinical research.
- The positive changes in the population's knowledge of and attitude toward cancer which are meaning their being more highly demanding but also better acceptance on their part of the treatments (Izquierdo *et al.*, 1996).
- A greater involvement on the part of our society, as revealed by the progressive development of cancer patient mutual support groups and volunteering.
- Progressive implementation of new diagnostic methods, drugs and more effective treatment strategies, despite their much higher economic cost.
- More highly complex treatments requiring multidisciplinary integration of the professionals and increasing the need for coordination, such as the combination of preoperative radio- and chemotherapy, etc. (Choy, 2003).
- Progressive closer link between applied and clinical research.
- The start of the technical debate as to the degree of centralization or concentration of healthcare resources required for the proper diagnosis and treatment of cancer, currently an ongoing debate (Hillner *et al.*, 2000; Smith *et al.*, 2003).
- The defining of cancer plans in different Autonomous Communities in their willing effort to set out a specific care-providing model for organizing cancer diagnosis and treatment.

The care standards in adult cancer diagnosis and treatment, as well as the critical points hindering these standards being met are discussed in the following sections hereinbelow. Lastly, the objectives and actions required for making headway in improving adult cancer patient care are set out.

3.3.2 Standards

- Independently of their place of residence and age, all patients with a well-founded clinical suspicion of cancer must have access, within a reasonable timeframe, to a test at a healthcare center, confirming or ruling out this disease. This clinical suspicion confirmation process must be carried out by means of priority circuits for accessing these diagnostic tests.
- In the case of a positive result confirming the suspicion, the subsequent diagnostic process must be carried out at a center which avails of the necessary laboratory, radiology and pathological anatomy resources and methods of sufficient capacity to guarantee that all patients diagnosed with cancer will avail of a quality extension study.
- All patients diagnosed with cancer must avail of an fully-planned, overall, personalized treatment plan. This treatment plan:
 - ✓ Must have been set out prior to the start of any treatment.
 - ✓ Must have been agreed upon with the participation of all of the specialists involved, within the framework of a tumor committee.
 - ✓ Must be in agreement with the clinical practice guide based on the best scientific evidence, provided that it be available.
 - ✓ Must be recorded on the medical record.
- All patients diagnosed with those types of cancer which are infrequent or which require a highly complex therapeutic technique shall be referred to a

hospital having specialists possessing sufficient experience to guarantee the best clinical outcomes.

- Those patients diagnosed with cancer must have access to quality cancer care, defined according to the following parameters.
 - ✓ Continued, coordinated healthcare, with a responsible medical specialist.
 - ✓ Multidisciplinary care, in which the contribution and responsibility of each specialty in the treatment is perfectly clear to the patient.
 - ✓ Equity in accessing the diagnostic and therapeutic resources.
 - ✓ Integration of psychosocial support into the treatment plan whenever necessary.
 - ✓ Existing protocols for the most frequent problems and treatments.
 - ✓ Integration of rehabilitation and social-occupational reinsertion in the care-providing process.
 - ✓ Integral care available with access to all of the services, from prevention to treatment and palliative care.
 - ✓ Measure the care-providing processes and their clinical outcomes for the purpose of guaranteeing the possibility of evaluating the care quality.
 - ✓ Capacity of evaluating and explaining to the public the resulting clinical outcomes.
 - ✓ Acceptable cost for the society of all care-providing processes.
- Those patients diagnosed with cancer must have access to the precise information for taking more active part, if they so desire, in the management of their own process.

3.3.3 Objectives

- All patients with a well-founded clinical suspicion of cancer must be able to have a first diagnosis confirmation test within the two weeks immediately following the suspicion having been established.
- All patients in which the existence of a cancer is confirmed must be seen at their hospital within one week's time in order for an overall treatment plan to be proposed to them.
- All hospitals which offer cancer treatment must have tumor committees for each one of the cancers for which they provide treatment, which renders a treatment decision prior to the treatment and in which all of the professionals involved in the cancer diagnosis and treatment process (or for each tumor, according to the case volume) take part.
- All hospitals which offer cancer treatment must have protocols adapted to the characteristics and circuits of each hospital based on the corresponding clinical practice guide for each type of tumor. This protocol must be public and must include the maximum lengths of time acceptable between each diagnostic or treatment procedure.
- All patients diagnosed must be treated within the framework of the corresponding multidisciplinary team, avoiding in all cases the duplication of resources and treatment variability within one same hospital. The treatment decision must be based on the corresponding clinical practice guide. The treatment process must end with an overall report which shall be furnished to the patient.
- All patients who must undergo treatment for their tumors must be treated within a reference timeframe as of the point in time of the treatment decision, which for the different types of treatments – not including emergency treatments - the following are proposed:
 - ✓ Surgical treatment: recommendable two-week timeframe.
 - ✓ Chemotherapy: recommendable one-week timeframe.
 - ✓ Radiation therapy: recommendable four-week timeframe, including the entire process of planning the treatment with ionizing radiations.

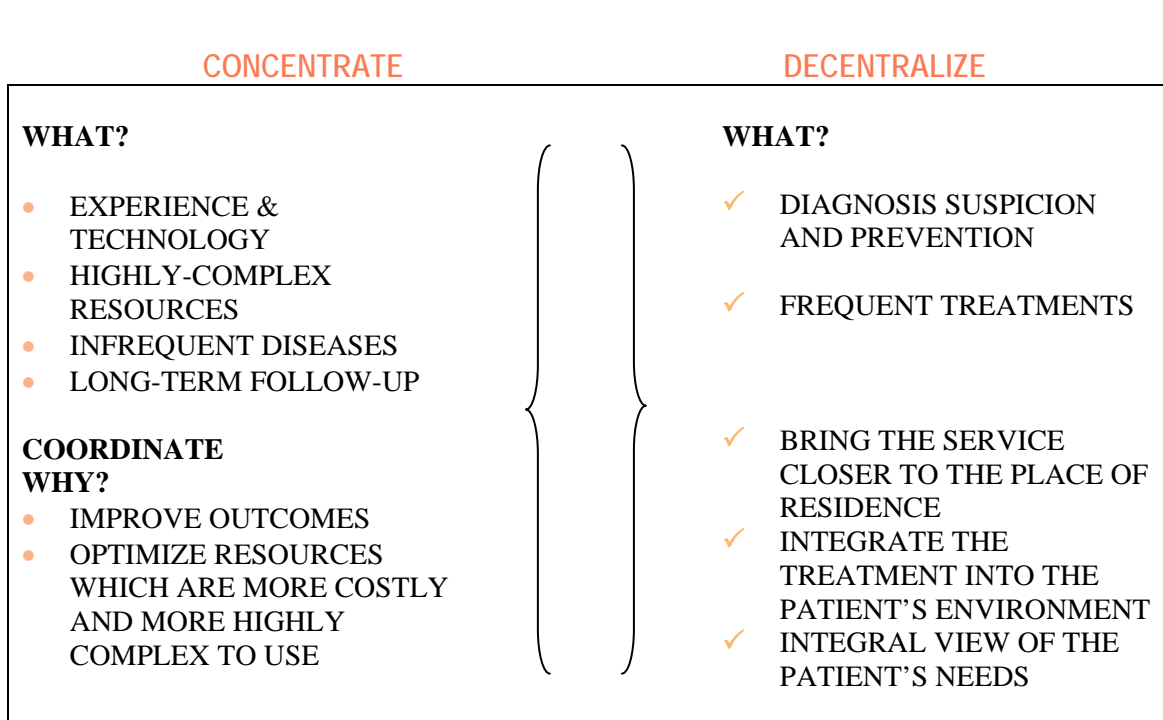
- Set out, based on the available evidence, the procedures which must (or should) be performed solely at specific clinical departments of reference hospitals for technology-related reasons or due to the better clinical outcomes related to the clinical experience in departments treating a large volume of cases.
- All hospitals which provide cancer treatment must have a hospital cancer registry or another methodology affording the possibility of evaluating the clinical outcomes of the patients treated in full or in part at the hospital in question and which will afford the possibility of evaluating at least the survival by stage at the point in time of the diagnosis, the percentage of relapses and the surgical mortality at thirty days or within the same hospital stay.

3.3.4 Critical points

- *Care continuity:* Problems in the care continuity of the patient's diagnosis and treatment process, both among levels of care or hospitals and among professionals of different specializations. This can mean unnecessary delays in implementing a therapy or conducting a diagnostic test or may mean not coordinating the most appropriate sequence of treatments.
- *Diagnosis and staging:* The quality, homogeneity and accuracy of the diagnosing and staging of the tumor determines to a great extent the treatment protocol to be employed and condition, in short, the prognosis of the disease. Therefore, a consensus is necessary in the coding and standardization of the pathological anatomy procedures and reports, as well as of all of the other procedures and reports on the diagnosis and extension process (Oncoguías, 2003).
- *Treatment decision:* The making of treatment decisions outside of a tumor committee with the presence of all of the specialties involved in the patient's diagnosis and treatment process (Haward *et al.*, 2003; Kaarjalinen *et al.*, 1989). This fact may lead to uncoordinated treatments or to an effective treatment not being indicated. This discussion as to what the most appropriate treatment combination may be is essential, above all in the starting treatment, the effective implementation of which is of prognosis-related value (Institute of Medicine, 1999) in the patient's survival (Smith *et al.*, 2001).

- *Variability*: The disparity in the clinical procedures and outcomes of the cancer treatments. The studies conducted, mainly in the surgical field (Peris *et al.*, 2001; Pla *et al.*, 2003) makes it possible to say that this variability is significant and has a bearing on the clinical outcomes.
- *Care volume*: The lack of adequate case care volume in highly complex procedures for acquiring sufficient experience in these procedures (Hewitt *et al.*, 2001; Hillner, 2001; Pla *et al.*, 2003). The hospitals performing these procedures serving as reference centers should be evaluated and their results periodically published. Examples of such procedures include: pancreatic cancer surgery, pelvic organ surgery and combined radio- and chemotherapy.

The necessary advisability of centralization and decentralization elements makes care-providing coordination key, which must be defined within the framework of cancer care planning. One approach to this problem is provided in the chart below:



- *Specialization:* The treatments which, although frequent, are highly complex, also require an appropriate specialization, experience and technologies on the part of the healthcare professionals. The clinical outcomes thereof must also be evaluated.
- *Evaluation of outcomes:* The evaluation of clinical outcomes must be one of the essential components of the multidisciplinary treatment activity making it possible to identify the areas for improvement and to be able to evaluate the actual benefits of the new treatment contributions (Lee *et al.*, 2000). This evaluation must be made based on a hospital registry which includes all of the cases treated at the hospital in question (Jensen *et al.*, 1991; Viladiu *et al.*, 1993).
- *Care-providing process evaluation:* The evaluation of the care-providing process (timeframe between diagnosis and treatment and among types of treatments) is important as a measurement of the quality of this process, but must go hand in hand with other variables (extravasations, percentage of conservative cancer treatment, degree of symptom control, etc.), as well as of the clinical outcomes (survival according to stage at diagnosis, surgical mortality, etc.) (Extramural Committee, 19990).
- *Equity:* The lack of sufficient infrastructure to carry out the radiation therapy treatments and, in some cases, the lack of more updated technology, such as, for example, 3D-planning so that the necessary territorial and access-related equity can be achieved (Esco *et al.*, 2003).
- *Innovation:* The incorporation of the new treatments and the evaluation of their clinical contribution must be made from a standpoint balancing a staunch position on the part of the healthcare system in favor of innovation in a top-priority field in health with the necessary evaluation of its cost-effectiveness ratio which must be evaluated independently (Smith *et al.*, 1993).
- *Training:* The promotion of continue training in the oncology field of the primary care professionals, as well as of the nursing staff which works in the care-providing services and of the technicians in radiation therapy.
- *Psychosocial:* The integration of the psychosocial aspects into the treatment of cancer (Fawzy, 1999).

- *Nutrition:* The incorporation of the nutritional support adapted to the patient's clinical evolution on an individualized manner.
- *Patient information:* The adapting of the information to the patient's wishes, as well as it being necessary to encourage the patient's participation in the management of their own process in addition to the corresponding informed consent in the diagnostic and treatment procedures in accordance with the laws in force. Out of all due respect for the values and the personal opinions of each cancer patient, including that of those who do not wish to be furnished with any information on their disease, a greater participation must be fostered on the part of the patients and the families in the decision-making process throughout the care-providing process, not solely out of the absolutely necessary respect for citizen sovereignty and will (Basic law 41/2002 of November 14th governing patient autonomy and rights and obligations concerning being informed and clinical documentation), but also out of the conviction that a greater involvement brings with it better outcomes in the treatment (Coulter *et al.*, 2003; Charles *et al.*, 1999; O'Connor *et al.*, 1999).

3.3.5 Actions

Improve patient access to the care resources

- Set out criteria and circuits for fast access to the fast diagnosis resources in the case of a well-founded clinical suspicion of cancer. Common protocol must be set out and evaluated for defining the criteria concerning clinical suspicion of cancer. (Martínez Pérez *et al.*, 2002).
- Promote each center integrating into a cancer care network in which all of the treatments a patient may require, even though they are not performed at the center in question will be available to the patient (Carlow, 1001; I., 1998; Kinkler, 2002; Livingston *et al.*, 2003). All patients, independently of their place of residence and of the hospital where the diagnosis has been made, must access, in a coordinated manner without suffering through unnecessary delays, all those care-providing mechanisms which they may require throughout the treatment process (i.e. radiation therapy, allogenic transplant of hemopoietic stem cells, liver metastasis surgery, rehabilitation, palliative

care). The reference hospital for the surgery and for the radiation therapy must preferably be the same so as to prevent any further transfers.

- Promote the reference centers establishing mechanisms for participation in the preparation of the protocols of the professionals of the centers in their care-providing network, which must offer the patients thereof coordinated care fully complying with the maximum waiting times defined as well as with the clinical practice guides. On the other hand, they must evaluate the outcomes thereof independently and make them known to the centers of the care-providing network into which they are integrated. Promote the setting out of homogeneous criteria for the collecting of biological samples and the processing thereof in tumor banks for purposes of research (Oosterhuis *et al.*, 2003), linked to the cancer research center network (www.rticc.org).

Guarantee the quality of the diagnoses

- Set out, by means of clinical practice guides prepared with the collaboration of the scientific societies, rational protocols and circuits for diagnosis confirmation and extension study.
- Set out, with the technical consensus of the scientific societies, anatomopathology report forms which include the coding system necessary for the purpose of guaranteeing the quality, homogeneity and accuracy of the diagnosis and staging of the tumor.
- Promote the development and the incorporation of the new molecular cancer diagnosis techniques of proven efficiency. It is necessary to avail of tumor banks in the anatomopathology departments, with samples identified and processed according to a standardized protocol avail for clinical and preclinical research.

Guarantee the quality of the treatments

- Guarantee that all of the center which treat cancer patients avail of and implement, within the framework of a multidisciplinary tumor committee, clinical practice guides developed based upon a consensus reached among the professionals, the medical technologies evaluation agencies and the

scientific societies with pre-established criteria for evaluation of the evidence. Promote the setting out of nursing clinical practice criteria for dealing with cancer patients.

- Set up, at those hospitals dealing with a major volume of cases, multidisciplinary medical team for the main types of cancer, coordinated by a medical specialist.
- Set up, in each Autonomous Community, a specific funding system for carrying out the Cancer Strategy objectives which includes the endowment of the new technologies required and the implementation of the new treatments which will guarantee their accessibility in equity, provided that it be an indication approved by the Spanish Drug Agency and the application thereof be included in the clinical practice guide. An information system which will afford the possibility of evaluating the use of these treatments in each treatment phase must be made available.
- Set out the obligation of the centers availing of a tumor committee which will ensure full compliance with the professionals from the different disciplines being involved in the treatment decision. According to the volume of cases, a specific committee may be set up for each type of tumor. The committee shall propose the maximum waiting times for each treatment at each center and shall evaluate compliance therewith.
- The hospitals must set out a “single entry” for each patient with a certain type of cancer, which, when diagnosed, facilitates the treatment decision being shared among all of the professionals from the appropriate specialties on a tumor committee. This single entry must be organized as a multidisciplinary team of professionals involved in all phases of the treatment and with a physician serving as the coordinator thereof.
- Guarantee that the cancer treatment will not discriminate against the elderly, save cases of frailty or comorbidity in which it is advisable to modify the treatment guideline.
- Recommend the inclusion of the standards and objectives defined in the corresponding Autonomous Community cancer plans.

Facilitate patient participation in the decision-making process regarding their process

- Regulate the right of cancer patients to a second opinion once an overall treatment plan has been suggested to them at a National Health System hospital.
- Develop, in collaboration with the scientific societies, the self-help associations, volunteers and information protocols for the patients affected, in which quality information on the different types of cancer, the advisable care, the cancer care services and the benefits offered, with the expectable care-standards are included.
- The medical ethics recommendations set forth under the laws in force make it mandatory to have the patient's informed consent in the cancer diagnosis and treatment interventions. Special emphasis must be placed on the patient's full comprehension of the information furnished by the physician.

Reference centers

1. In the procedures proposed in following, the National health System shall determine one or more national reference centers for performing highly complex, infrequent procedures, for which additional funding shall be provided in order to be able to appropriately prioritize these treatments.

The procedures proposed are as follows:

- Carbon proton and ion treatment.
- Ophthalmic brachytherapy
- Non-relative allogenic transplants
- Others determined by the Interterritorial Council at the proposal of the NHS Cancer Strategy.

2. Similarly, the Autonomous Communities shall determine one or more autonomic reference centers for performing highly complex, infrequent procedures, such as:
 - Surgery intended to cure esophageal cancer
 - Surgery intended to cure pancreatic cancer
 - Surgery of liver metastases
 - Combined pelvic organ and cancer surgery
 - Radio-guided surgery
 - Central nervous system and extracranial radiosurgery
 - The complex radiation therapy and chemotherapy treatments
 - Others which are determined by the corresponding Autonomous Community cancer plans

Set up care quality evaluation systems

- Set forth on a regulatory basis, within a one-year period, the existence of hospital cancer registries at the centers so deemed (Jensen *et al.*, 1991; Viladiu *et al.*, 1993).
- Set out, whilst the NHS Cancer Strategy is in effect and by way of a consensus among the different Autonomous Communities, the minimum standards necessary for the hospital cancer registries in order to guarantee their homogeneity and comparability so that they will afford the possibility of availing of reliable data at least on the survival, percentage of relapses and surgical mortality according to stages.
- Set up, by way of a consensus among the different Autonomous Communities, a permanent system for the evaluation of reference centers and professional teams which will afford the possibility of the minimum activity of certain treatments in which the case volume has a bearing on the clinical outcomes being permanently evaluated on the part of each Autonomous Community (Pla *et al.*, 2003).

3.3.6 Examples of good practices

TREATMENT PROCEDURES REQUIRING SPECIALIZED CENTERS. CATALONIA.

A number of procedures have been proposed which, due to their complexity and the infrequent number of cases, may benefit from being performed solely at certain hospitals within the framework of the 2001-2004 Catalanian Master Cancer Plan. These procedures have been selected based on two criteria: review of the existing literature in the field of surgical procedures and specific technological or know-how needs which are required solely for a limited number of patients. The list of procedures selected is as follows:

- Esophageal cancer subject to a surgical approach.
- Pancreatic cancer
- Surgical treatment of liver metastases
- Operable lung cancer
- Pelvic exenterations
- Radiosurgery
- Neurooncology
- Sarcomas
- Preoperative radio-chemotherapy of rectal cancer
- Hematological tumors which are candidates for allogenic transplants
- Germ cell tumors of poor prognosis
- Genetic counseling for hereditary cancer

The hospitals which perform these procedures must be evaluated periodically regarding both the process as well as the process outcomes. The evaluation indicators include the following: mortality at 30 days from the surgical intervention or within the same hospital stay; resectability index (patients with resection performed as compared to total number having undergone surgery) of less than 10%; relapse-free survival by stage at the point in time of diagnosis.

CANCER GUIDES IN CATALONIA

The cancer guides have been prepared with the participation of over 200 professionals in Catalonia to serve as a framework of reference of the Catalonian Health Service treatment offer for the purpose of advancing in treatment equity. Cancer guides have been drafted for breast cancer, colorectal cancer, lung cancer and non-Hodgkin's lymphomas. These guides have been reviewed by international experts with the collaboration of the Catalonian Academy of Medical Sciences.

The preparation process included the participation of the experts from different hospitals, coordinated by the Catalonian Medical Technology and Research Evaluation Agency, which has provided the methodological support. The work concluded with a public discussion session with the professionals involved, in which more than 350 professionals took part. The following guides have also been prepared: prostate cancer, laryngeal cancer, ovarian cancer, pediatric cancerous brain tumors and Hodgkin's lymphoma.

Information: www.aatrm.net

THE PATIENTS' VIEW: AN KEY ASPECT OF CANCER CARE

Cancer care quality must also be measured from the perspective which may be provided by the patients and not confining the evaluation of the care outcomes solely to survival or quality of life. In our country, no systematic studies on the patients' view have been conducted, although the findings of what is probably the first study employing a qualitative methodology (FUNDSIS) have recently been published. In synthesis, from the patients' standpoint, a cancer care quality model in international experience would be of the following characteristics:

- Access to coordinated, multidisciplinary cancer care services.
- Confidence in the professionals providing the medical care.
- Perception so that the healthcare professionals will respect, listen to and work in the interest of the patient.
- Receptivity to the questions concerning the disease, its causes, treatment and consequences, as well as the ability to state their preferences related to the treatment.
- Clear understanding of the diagnosis and access to the information which may serve to better this comprehension.
- Knowledge of all of the treatment options and of the benefits and risks related to these options.
- Confidence in the option chosen being the appropriate one, offering the best option for an optimum clinical outcome in accordance with the patient's personal preferences.
- Availability of a responsible healthcare professional with the capacity to render accounts for the results, to organize this treatment plan in collaboration with each patient.
- Guarantees of the care quality clinical practice guides set out being fully complied with at all healthcare centers.

Source: Optimizing cancer in Australia. Canberra: National Cancer Control Initiative. 2003.

**SYSTEMATIC PRIMARY CARE DATA COLLECTION.
THE CANCER PATIENT INCIDENCE AND MORTALITY REGISTRY (RIMCAN)**

The Cancer Patient Incidence and Mortality Registry (RIMCAN) was started by the Spanish General Practitioners' Society in 1991. It is based on the reporting of the cases of cancer-related incidence and mortality in the population seen by the general practitioners/family physicians voluntarily participating in the study. The physicians participating within the 1991-2001 period have totaled 129-447 (approximately 200 having taken part continuously since 1993). A total of 70% of these physicians practice in Castile and Leon, 85% doing so in populations of fewer than 10,000 inhabitants.

The most specific aspect of this registry is that it avails of abundant information related to the cancer patients from the general practitioner's/ Family physician's perspective, some of the most outstanding being:

- Most frequent tumor localizations, distribution by gender and age, form of diagnosis, initial symptomology and diagnosis-treatment timeframes observed in patients seen in primary care practices of the collaborating physicians.
- Most frequent tumor localizations, distribution by gender and age, of those patients having died of cancer in the population seen by the collaborating physicians: timeframe between diagnosis and death, place of death, major final symptoms and their degree of control, pharmacological treatment in terminal phase, opinion with regard to the quality of the care provided, bedriddenness and need of home care.

A total of 4,361 new cases and 2,531 cases of death have been included in this registry within the 1991-2001 period.

The coordinator is Miguel A. Ripoll (mripoll@semg.es).

Information from the 1991-2001 data and from the RIMCAN-related publications at:

http://www.semg.es/Documents/Informe_RIMCAM_10.pdf

SECOND OPINION PROGRAM. ANDALUSIA

In Andalusia, all patients diagnosed with cancer, degenerative neurological diseases and rare diseases (<5/10,000 inhabitants) are entitled by law (Decree 127/2003) to a second a opinion. The second opinion is requested through the patient management section of the patient's original hospital, being remitted to a central office located in Jaén (copies of the reports and of the supplementary examinations, analyses, anatomopathology and the radiological images are forwarded). From this central office, one of the experts designed by the Andalusian Health Council within the Public Health System (8-9 in all in Andalusia) is contracted, and the expert writes a report which is furnished to the patient through the patient management department. This report must be drafted based on the information received, additional information being requested being considered solely exceptionally. If the second opinion agrees, the process ends here. If the second opinion does not agree, recourse is then taken to a report issued jointly by three experts, including the first expert to whom the case had been referred.

The commitment is for there to be a maximum 30-day lapse from the date of request to the date on which the patient receives the second opinion (one of the program objectives being to shorten this timeframe immediately). As matters currently stand, a total of 140 second opinions were requested throughout the August1-September 30, 2003 period, the vast majority of which agreed with the primary plan offered to the patient.

Information: <http://www.juntadeandalucia.es/servicioandaluzdesalud>

3.4 CHILD AND ADOLESCENT CARE

3.4.1 Background information

In Spain, approximately 1,000 children are diagnosed with cancer every year (Pollán M *et al.*, 1995; Parkin *et al.*, 1998). A serious, progressively more curable disease requiring a complex, long-term treatment often taking up a long period in the child's life. A disease which has a determining bearing on a family's personal and social structure. A child cancer plan must therefore be set out from the start as integral care of the child and of the child's surrounding environment.

In Spain today, one out of every 2,000 adults is a survivor of childhood cancer. Thus the objective of pediatric oncology can be no other than to achieved that the child cured of a cancer will grow up to be an adult capable of leading a normal life from the physical, psychological and social standpoints. An adult with the same rights and obligations as their cancerless peers.

In this regard, it is important not to overlook adolescents with cancer, which poses a number of problems stemming from the fact of being seriously ill during that time in life when we human beings fight most for our independence and own self-reliance. The adolescents in this situation are more dependent on their parents, and the disease suddenly halts their life's aspirations on the intellectual, sports-related and social planes. It is therefore recommended that adolescent care be carried out in pediatric oncohematology departments which avail of the necessary schooling and psychosocial care infrastructure.

The care for children diagnosed with cancer must be provided within the hospital environment, in a pediatric oncology department in which specialized medical and nursing staff will guarantee the integral care of the patients and their families (American Academy of Pediatrics. Section on Hematology/Oncology, 1997; Hammond GD, 1986). The complexity and specificity of the treatment so require. A child's survival depends on facts as fundamental as this.

The oncohematology department must be integrated into the pediatrics department, working in coordination with the rest of the pediatric specialties and

departments in the hospital. The requirements for a pediatric oncohematology department have been set out by the International Society of Pediatric Oncology (SIOP) (Thaxter G et al., 2002) and are specified in Table 3.4 below.

TABLE 3.4 THE INTERNATIONAL SOCIETY OF PEDIATRIC ONCOLOGY (SIOP) RECOMMENDATIONS FOR THE ORGANIZATION OF A PEDIATRIC ONCOLOGY DEPARTMENT

- All children and adolescents with cancer must have access to a diagnosis, treatment and follow-up by a multidisciplinary pediatric team which is coordinated by pediatricians, pediatric oncologists, pediatric surgeons and radiation therapy oncologists. Special attention must be devoted to adolescents and young adults.
- The pediatric oncology department must operate integrated into a national and/or international organization in order to facilitate the notification and coordination of the new treatment and research methods. There must be material and human support for participation in childhood cancer clinical trials and epidemiological registries.
- Pediatric oncology departments must provide treatment for a sufficient number of patients in order to guarantee an infrastructure which includes:
 - ✓ Pediatric surgery
 - ✓ Radiation therapy oncology
 - ✓ Pediatric intensive care
 - ✓ Pathological anatomy
 - ✓ Supporting nutritional, psychosocial and rehabilitation treatment

The pediatric oncology department operating scheme is:

- Hospitalization area, qualified for:
 - ✓ Complex medical treatment and access to central channels
 - ✓ Monitoring prolonged drug infusions

- ✓ Providing care for seriously-ill, immunodepressed or terminal-stage children
- ✓ Handling and preparation of chemotherapy
- ✓ Completing the medical record
- ✓ Accommodating the parents in the department or in the nearby area
- ✓ Providing psychosocial and spiritual support

- Day hospital:
 - ✓ Out-patient chemotherapy treatments
 - ✓ Out-patient support treatments (transfusions, antiemetics, fluid therapy)
 - ✓ Clinical observation of patients for a few hours

- Consultation:
 - ✓ Patient follow-up
 - ✓ Fast laboratory and radiology access

- Necessary human and technical means:
 - ✓ Nursing staff accredited in pediatric oncology
 - ✓ Childhood radiology including CT,MR, echography, angiography, etc.
 - ✓ Laboratory qualified for tumor markers and drug monitoring.
 - ✓ Chemotherapy
 - ✓ Pharmacy familiarized with the use of chemotherapy. Laminar flow bell.
Availability of parenteral feeding methods.

- Pediatric tumor committee.

- The pediatric oncology department must assure round-the-clock operation (hospitalization)

- The pediatric oncology department must assure the continuing training of its professionals.

The International Society of Pediatric Oncology (SIOP) recommended in due course that a pediatric oncology department should treat a certain number of patients per year. However, it is not so much the number of patients/year, but rather the multidisciplinary infrastructure that these departments require, which has an impact on good care being provided for these children.

It is also important to further expand upon the collaboration with primary care and regional hospitals such that, by joining forces, the children will not have to move to the large-scale hospitals for studies and treatment. This entails defining the role which the different levels of hospital care complexity are to represent in providing care for children and adolescents undergoing cancer treatment and in carrying out a plan for coordinating these different levels.

Three levels of care can be established for children and adolescents with cancer:

Level 1. – Comprised of primary care pediatricians and regional hospitals which may provide care for these patients in very precise situations, at all times coordinated with their reference pediatric oncohematology department.

Level 2. – Pediatric oncohematology departments located in pediatric services/areas availing of the infrastructure set out by the SIOP (Table 3.4).

Level 3.- Pediatric oncohematology departments which additionally avail of very specific treatment options (Ex.: non-relative bone marrow progenitor cell transplants or certain neurosurgery techniques, traumatological surgery, radiation therapy). The Level 2 departments may refer a patient to these reference departments for a certain treatment in particular.

Childhood cancer is a chronic disease which often leaves major medium and long-range physical and psychological sequelae . The psychosocial care provided to these children and their families starting as of the point in time at which they are first diagnosed, coordinated with the medical care, aids toward a better tolerance of the treatment and mitigates the sequelae. Therefore, the help with schooling, social needs, psychosocial support, etc. must be provided. Additionally, healthcare and social follow-ups of the survivors is necessary, as is also the follow-up and support for those families who have lost a child to cancer.

Spain is one of the European countries in which the healthcare provided for children diagnosed with cancer is excellent overall. Getting the national protocols coordinated by the Spanish Societies of Pediatric Oncology (SEOP) and Pediatric Hematology (SEHP) under way and their collaboration in international protocols has determined the survival of a child diagnosed with cancer in Spain being similar to that of the countries in our environment (Pollán *et al.*, 1995). The survival data of the National Childhood Tumor Registry (RNTI-SEOP) thus states: the relative five-year survival rate for all tumors is 73.1% (Peris R *et al.*, 2003). Special emphasis must be placed on the need of improving the preferential medical care circuits in view of the well-founded clinical suspicion of cancer in young children and in the continuing training of the pediatricians and family physicians concerning pediatric oncology pathology, which, although infrequent, is the second cause of deaths among children ages 0-14 in Spain (Pollán M *et al.*, 1998).

Clinical, basic and epidemiological research in pediatric oncology must be coordinated among the different pediatric oncohematology departments in the country by means of participation in the networks devoted to the topic of cancer. The molecular diagnosis of pediatric leukemias and solid tumors makes it possible to define prognostic factors and to provide personalized treatment for the patients (Triche TJ, Sorensen P, 2002).

The study of the factors predisposing a person to develop cancer during early childhood is a topic of utmost interest. Taking the familial cancer syndromes separately, which represent solely 4%-10% of the cases (Knudson AG, 2003), risk factor research is revolving around environmental factors. The European Commission “Environmental and Health” strategy (Brussels, 11.6.2003) recently established one of the main priorities within the contents of its first cycle (2004-2010) as being the betterment of the understanding of the relationship between different environmental factors and childhood cancer. There are publications in this regard which make reference to a rise in the incidence of childhood cancer related to pre-conceptual, conceptual, transplacental and postnatal exposures (Smith MA, Gloecker LA, 2002; Doyle P *et al.*, 1998). There are working groups in our country currently focusing on this subject (Ferris I Tortajada J *et al.*, 1999).

Lastly, all care provided for young children diagnosed with cancer must be governed by bioethical criteria which will safeguard their personal dignity and quality of life from diagnosis to their cure or death.

3.4.2 Standards

- All children and adolescents diagnosed with cancer must be provided with complete, integral, multidisciplinary care and have access to the current national and international diagnosis and treatment protocols.
- The care of these children in multidisciplinary pediatric oncohematology departments which meet the International Society for Pediatric Oncology (SIOP) requirements set out in Table 3.4 must be guaranteed.
- Those children and adolescents cured of a cancer must be able to grow up to be adults leading a normal life, integrated into the society of their time. For this purpose, it is indispensable that psychosocial care be provided for these patients and their family members starting as of the point in time of the diagnosis.

3.4.3 Objectives

- Assure the children and adolescents diagnosed with cancer being provided with integral treatment of their disease.
- Facilitate the access of children diagnosed with cancer in Spain to the diagnosis and treatment protocols regarding which a consensus has been reached among the national and international scientific societies.
- Guarantee psychosocial care to these children and their family members at the hospital, at home and in school starting as of the point in time of the diagnosis.
- Promote the epidemiological and clinical follow-up of the pediatric cancer survivors on a lifelong basis in collaboration with the National Childhood Tumor Registry (RNTI-SEOP).
- Conduct a study on the predisposing environmental factors in childhood cancer.
- Promote the implementation of bioethical criteria in the care provided for children diagnosed with cancer.

3.4.4 Critical points

- In Spain, an undetermined percentage of children are not as yet being provided with care in pediatric oncohematology departments. This fact is inferred from the National Childhood Tumor Registry (RNTI-SEOP) data with regard to the currently-existing differences between the anticipated incidence rate and that actually found to exist in the different oncological processes.
- *Multidisciplinary pediatric oncohematology departments.* In some Autonomous Communities, only a very few pediatric services /departments avail of the infrastructure necessary for providing the proper care of children diagnosed with cancer, whilst these departments tend to group together in other Communities. The patient referral circuits for complex treatments – non-relative donor bone marrow transplants, certain pediatric neurosurgical or traumatological techniques – are not protocolized.
- *Psychosocial aspects and rehabilitation in childhood and adolescent cancer.* At most hospitals in our country, no psychosocial care is provided for the children and adolescents diagnosed with cancer. At those hospitals where the families are provided with this support, it is funded by groups of parents of child cancer patients (Federation of Childhood Cancer Parent Associations) and some NGO's (Spanish Association Against Cancer).
- The children undergoing cancer treatment requires the presence of an adult (mother or father) during the hospitalization and home care periods. This entails one of their parents taking leave from work, with the serious consequences this involves for the family economy.
- *Study of predisposing factors for developing a childhood cancer.* The major resource for the epidemiological study of childhood cancer in Spain, the National Childhood Tumor Registry (RNTI-SEOP) does not avail of the infrastructure at this point in time for expanding its activity to the study of environmental factors which have a bearing on childhood cancer and to the registry of long-range sequelae.
- It is advisable to promote greater interest in the importance of bioethical criteria in the care provided for childhood cancer patients as far as the clinical and basic research protocols and informed consents are concerned.

3.4.5 Actions

- Inform those responsible for the pediatrics services/areas of the different Autonomous Communities as to the need of guaranteeing the care of those children and adolescents (0-18 years of age) diagnosed with cancer in Spain in multidisciplinary pediatric oncohematology departments. Demand full compliance with the recommendations of the International Society for Pediatric Oncology (SIOP) set out in Table 3.4. In this regard, it is important that the following finer details be set out:
 - ✓ *Pediatric oncology nursing staff.* Recommend training in pediatric oncohematology to the Spanish Oncology Nursing Society (SEEO) and that the pediatric oncohematology departments have at least 25%-30% of the nursing staff trained.
 - ✓ *Radiation therapy.* Recommend to the Autonomous Communities that the radiation therapy departments avail of the appropriate resources for properly treating children. The requirements are: staff specialized in radiation therapy oncology trained for treating childhood tumors, availability of pediatric anesthesia for performing those treatments which require sedation and updated technology consisting of: linear accelerator, CT simulation and 3D dosimetry.
 - ✓ *Surgery.* At the reference hospitals, it is necessary to avail of pediatric surgeons possessing specific training in oncological surgery.
 - ✓ Continuing training of the personnel involved in providing care for these children.
- Recommend to the scientific societies related to childhood cancer that they implement the coordination and communications among all of the pediatric oncohematology departments in Spain in order for the protocols of the basic and applied research which is conducted in our country to be a model of cooperation between basic and clinical researchers in the fight against childhood cancer. In this regard, the centralization of the pediatric tumor banks, the coordination in the implementation and measurement of outcomes of the clinical protocols currently in use and those which are used in the future and participation in studies of an epidemiological nature on pediatric cancer are fundamental.

- The health services of the different Autonomous Communities must guarantee the provision of care of the psychosocial aspects and rehabilitation of the children and adolescents diagnosed with cancer. To this end, they must:
 - ✓ Support initiatives for the purpose of informing the patients their families and the schools concerning this disease and its treatment in order to facilitate the integration of the children with cancer into their school environments. It must not be overlooked that going to school is, for children, the best indicator of their lives “getting back to normal”, and it is there where they usually come up against the problems which most affect them. Close collaboration with the parent groups set up at each hospital and supporting these groups being set up at those centers where there are none, knowing their resources for better patient care (shelters for those families whose homes are far away from the hospital, entertainment and training activities, etc.).
 - ✓ Guarantee specialized psychological care starting as of the diagnosis and foster fluid communications between the psychologist and the different professionals forming part of the children’s life (school, pediatrician and family physician).
 - ✓ Guarantee the social care of the patients in regard to the needs entailed in a lengthy hospital stay in the functioning of a family. In this regard, coordination with the parents’ associations and the NGO’s is fundamental.
 - ✓ Rehabilitation during their hospital stay and when the children return home, in coordination with the resources existing nearest to their homes.
 - ✓ Setting up an economic support mechanism for the family during those times in which it is necessary to take leave from work in order to care for a sick child.
- Stress upon the pediatric oncohematology departments the need of registering the patients with the National Childhood Tumor Registry (RNTI-SEOP). Further strengthen said registry for the collecting of data on the sequelae, on a long-range basis, of the treatments which are currently administered.

- Include in the National Childhood Tumor Registry dynamic the collecting of data from the environmental factors study (environmental record) which may be related to cancer during childhood and adolescence. The work done to date by this organization makes it a reference point for the gathering of data which not only have a bearing on the patients and their families, but are also of interest to Spanish society as a whole.
- Guarantee that the care provided to the children diagnosed with cancer is governed by bioethical criteria, based on the respect for their personal dignity and their frailty as individuals” incapable of consenting” when minors. Regarding the laws currently in force in our country, demand that they be obeyed and fight for the rights of the child and the patient be totally respected (Law 41/2002).

3.4.6 Examples of good practices

NATIONAL CHILDHOOD TUMOR REGISTRY (RNTI-SEOP)

The National Childhood Tumor Registry (RNTI) is the reference point for knowing the epidemiological data on this disease in Spain. This Registry has been recording cases since 1980, with 13,199 cases registered, it is, along with Great Britain and Germany, one of the largest childhood tumor registries in Europe. It is currently registering an average of 625 cases annually. Its quality indicators are: the microscopic verification of the diagnosis in more than 9% of the cases, active follow-up for 5 years in more than 90% of the cases and a 71% coverage nationwide in Spain. This Registry totals 100% coverage in Aragon, the Balearic Islands, Catalonia, Navarra and the Basque Country.

Information: Dr. Rafael Peris, coordinator.

SPANISH PEDIATRIC ONCOLOGY AND HEMATOLOGY SOCIETIES

Protocols having been gotten under way by the SEOP and SEHP starting as of 1989 has determined childhood cancer survival in our country being similar to or higher than that of the countries in our environment.

Some of the most noteworthy groups of childhood cancer diagnosis and treatment protocols are the acute lymphoblastic leukemia (LLA-SHOP) , neurblastoma and brain tumor protocols.

Website: <http://www.seop.org/welcome.htm>

FEDERATION OF CHILDHOOD CANCER PARENT ASSOCIATIONS

The Spanish Federation of Cancer Parent Associations has been revindicating the role of parents in the process of caring for their sick children since it was first organized in 1990. This Federation plays an unquestionable role in Spanish pediatric oncology. On the basis of the European charter for children in hospital adopted by the European Union in 1986, they demand full compliance with Article 3 thereof: “Accommodation should be offered to all parents, and they should be helped and encouraged to stay. Parents should not need to incur additional costs or suffer loss of income.” This organization is based on the voluntary work of parents and family members of children with cancer. It has an agreement in effect with the Government Administration so that its programs and services can be carried out at the hospitals. Some of its most noteworthy programs include psychosocial support, shelters, training programs, education (home schooling), leisure and free-time activities and social volunteering.

federacion@cancerinfantil.org

PEDIATRIC ENVIRONMENTAL HEALTH DEPARTMENT OF THE “HOSPITAL MATERNOINFANTIL UNIVERSITARIO LA FE DE VALENCIA. (FERRIS I TORTAJADA J, ORTEGA GARCÍA JA and MARCO MACÍAN A)

This department works on gathering data by way of the pediatric environmental record in children with cancer carried out by trained pediatricians with a sensitivity to and experience in pediatric environmental health, pediatric oncology and basic epidemiology for the purpose of identifying and/or quantifying, whenever possible, the probable environmental carcinogenic agents. This data will be obtained in close collaboration with the National Childhood Tumor Registry. One of its objectives is the study of and pediatric training in the environmental factors involved in childhood cancer, the identification of carcinogenic products unknown to date as being related to child and adolescent cancer, better the knowledge of child susceptibility to environmental carcinogens and determine those which are preventable, if any.

The “Hospital Infantil Universitario La Fe” Pediatric Environmental Health Dept. website:

<http://www.pehsu.org> and [http://www.socvaped.org/enlaces\(saludmedioambiental.htm](http://www.socvaped.org/enlaces(saludmedioambiental.htm)

**SOLID CHILDHOOD TUMOR RESEARCH NETWORK (RITSI)
COORDINATOR: DR. J. SANCHEZ DE TOLEDO.
HOSPITAL VALLE DE HEBRON**

This project consists of the study of the molecular pathology of solid childhood tumors, the contribution thereof to the diagnosis and to the personalization of the treatment. Its objective is the study of the molecular biology of solid childhood tumors. The samples of the tumor diagnosed anywhere in Spain are sent to the node that is more specifically studying the specific tumor in question in particular. At the same time, a solid childhood tumor bank is being created so that the researchers may access these tumors when conducting a study. This network currently consists of nine nodes: 1. Pediatric Oncology. Hospital Valle de Hebrón (MI: Soledad Gallego). 2. Pediatric Oncology. Hospital San Juan de Dios (MI: J. Mora). 3. Pediatric Oncology. Hospital Cruces (MI: A. Navajas). 4. Biomedical Research Institute. Hospital Infantil La Paz (MI: A. Pestaña, J. Alonso and P. García-Miguel). 5. Hospital del Niño Jesús (MI: M. Ramírez). 6. Cancer Research Center. Salamanca (MI: E. de Álava). 7. Pediatric Oncology. Hospital Virgen del Rocío (MI: D. Segura). 8. Anatomopathology Department. University of Valencia (MI: S. Navarro). 9. Pediatric Oncohematology. Hospital La Fe. Valencia (MI: V. Castel). The National Childhood Tumor Registry (MI: R. Peris) is also taking part.

JORDI GIRALT LÓPEZ PEDIATRIC RADIATION THERAPY GROUP

[mailto: jgiralt@cw.vhebron.es]

The pediatric radiation therapy group is comprised of specialists in oncological radiation therapy who devote part of their time to treating childhood tumors. There are representatives from a majority of the Autonomous Communities, Madrid (3 representatives) and Andalusia, Catalonia and Galicia (2 representatives each) being those having the most representatives. The objective is to have a space for sharing which will make it possible to improve the treatment of childhood tumors: consultation of complex cases, discussion of new treatments or clinical trials. In this regard, the indications for radiosurgery in pediatric tumors have been revised, a study being made of relapse patterns in bone marrow tumors. In collaboration with the SEOP childhood tumor group, getting a treatment protocol for high-degree gliomas is currently under study. A study is also currently under way concerning radiation therapy in childhood Hodgkin's disease.

3.5 QUALITY OF LIFE

3.5.1 Background information

Highly important advances have been being made over the past few years in the study and treatment of cancer which are making it possible to cure a progressively large number of patients in addition to lengthening the survival rate among most of the patients who are not cured. All this is giving rise to some highly important changes in the patient clinical profile regarding both the treatment-related and care-providing aspects.

The current demands of society at large and of the patients in particular are progressively greater, the term “quality of life” now having become popular. The term “quality of life” however refers more to user satisfaction than to the quality of the care provided, although quality care is undoubtedly necessary in order for user satisfaction to be achieved.

The first problem encountered when discussing quality of life is to precisely define this concept. Currently, most authors agree as to the multidimensionality and subjectivity of the quality of life concept and propose taking at least physical, functional, psychological, socio-familial and economic-occupational well-being into account.

One must not overlook the fact that quality of life entails individuals and therefore subjective aspects (the parameters are not of the same importance in all patients) and time-related aspects (possibly changing in one same individual throughout their life). Nonetheless, a number of *psychological, physical and socio-occupational* phenomena take place in quite a major percentage of patients diagnosed with cancer which objectively alter the quality of life of the patients suffering from these phenomena.

The quality of life evaluation is especially relevant in oncology for several reasons:

- There is a linear relationship between severity, evolution of the disease and the quality of life in all patients, as we know that quality of life depends

both on objective medical factors and on the patient's subjective and emotional factors.

- The psychological impact of the diagnosis for the patients and their family members, the dependency on the health system, the expectations and reality of the treatments, the evolution of the disease, etc.
- The physical impact of the disease and of the treatments.
- The growing number of survivors of the disease and the progressive lengthening of the survival time of those who do not evolve positively, this being a time during which it is possible to help those having this disease to have a desirable existence.
- The expectable quality of life must be, for the physician, one of the determining aspects in choosing the type of treatment to be used and one of the elements concerning which the patient must be informed when making decisions.

The quality of life is worthy of special mention in elderly patients with cancer, in which, given their frailty in both physical and psychological terms, this concept takes on a greater dimension.

Psychological aspects

Cancer is a serious, complex disease which has a bearing on all aspects of a person's life. It means a break in the organization, pace and style of life and entails not only an emotional impact but also a psychological impact in the three dimensions thereof: cognitive, emotional and behavioral. And this is not so only for the person who has the cancer, but also for their entire family and social environment, as well as for the professionals who are providing their care. This occurs not only at the point in time of the diagnosis, but throughout the entire process, even for years after having completed the process, turning into emotional sequelae thereof. The psychological repercussions of the disease interfere negatively both on the quality of life of the moment but on the ability to recover from and adapt to this disease.

The data included in different international-level studies show that more than 50% of the patients shown psychopathological signs and symptoms due to the high degree of stress with which they must cope during and after their disease, which lessen their quality of life and make the intervention of a specialist necessary for the proper handling thereof. It has been found that 20%-35% of the patients with cancer go so far as to display *psychopathological morbidity* following the diagnosis, and that these percentages rise during the treatments and hospitalization.

Apart from the above, being diagnosed with cancer means a change in the *family dynamic* which requires a major degree of flexibility on the part of the different family members for the purpose of adapting as best possible to the demands which this disease and its treatments impose. The changes and alterations which affect one member of the family system have a bearing, in turn, on the other family members.

In addition thereto, the medical care of people with chronic, serious, potentially fatal diseases such as cancer as well as dealing daily with physical deterioration, generate major degrees of stress and emotional turmoil among the members of the *healthcare staff* which not only alter the psychological well-being of the person who has the cancer but can also affect the care provided to the patient, the relations with fellow workers and the relations with family and friends. When this occurs, the professionals cannot function efficiently and objectively, and the care they provide to both the patient and the patient's family deteriorates and becomes significantly dehumanized.

The stress and feelings of impotence that are generated by caring for cancer patients may lead, in some cases, to what is known as the "professional burnout" syndrome.

Physical aspects

Regrettably, in order to attempt to achieve the cure or lengthen survival of many patients diagnosed with cancer, it is necessary to apply treatments which often entail sequelae or side-effects.

Surgical treatment must be radical and sometimes involves major physical sequelae. Thus, over the past few years, with the objective of improving function and

aesthetics, organ conservation techniques being employed on one hand and, on the other, the use of techniques for reconstructing the anatomical flaws caused either by the tumor proper or by the treatments, is being fostered.

Radiation therapy often entails non-severe side-effects (xerostomy, radiodermatitis, mucositis) and, very rarely, may cause serious side-effects (necrosis, fibrosis, fistula, myelitis, mutagenesis, etc.) which alter the patients' quality of life to a greater or lesser degree.

The side-effects of chemotherapy (hematological, digestive, dermatological, cardiac, neurological, pulmonary, hepatic, renal toxicity, hypersensitivity, etc) are one of the aspects most feared by cancer patients which also clearly alters their quality of life.

Socio-occupational and economic aspects

In cancer patients, there are a number of socio-occupational and economic aspects which must be taken into account in order to maintain the quality of life. For all these reasons, it is necessary that the quality of life of the patients diagnosed with cancer, the repercussions of the different treatments and their social and occupational adaptation being considered. Given that terminal patients (palliative care) are dealt with in other sections, reference is not made here to these patients, but rather focusing on the subject of the evaluation of the quality of life both as personally perceived and in the evaluation of the structures for accompanying the patients, of the processes and of the outcomes.

In short, this would be a matter of dealing, in an overall manner, with the psychological adaptation or adjustment to the disease, to the treatments and their side-effects, as well as the physical rehabilitation, socio-occupational reinsertion and rehabilitation of the patients diagnosed with cancer.

3.5.2 Standards

All of the patients diagnosed with cancer, as well as their family members and the healthcare personnel providing their care are provided with the necessary care to guarantee the appropriate treatment of the disease and of the physical and psychological sequelae involved therein, starting as of the diagnosis up to their recovery or death.

3.5.3 Objectives

- Control the sequelae and side-effects of the treatments.
- Provide the patient, family members and healthcare personnel with psychological care.
- Facilitate physical rehabilitation for the physical sequelae of the disease and its treatments.

3.5.4 Critical points

On the psychological level

- Cancer entails a major psychological blow not only for the person diagnosed with cancer but also for their entire family and social environment, as well as for the professionals providing care for the patient. And this is so not only at the point in time of the diagnosis, but throughout the entire process.
- A total of 20%-30% of all patients with cancer display psychopathological morbidity following the diagnosis, 37%-40% of those taking chemotherapy and 35%-50% of those who are hospitalized. And more than 50% display symptoms of stress which complicate coping with and recovering from this disease.
- Scientific evidence exists supporting the positive effects of the psychological interventions on emotional adjustment to the disease and on the quality of life, as well as on the prevention of the professional burnout syndrome.
- Cancer patients' families sometimes needs as much psychological support and help as the patients themselves.
- The healthcare personnel also displays emotional alterations which sometime require psychological support.

- The psychological needs of the patients, family members and healthcare personnel are not currently given due consideration.

On the physical level

- Sequelae and side-effects of the treatments:
 - ✓ Surgery: amputations and aesthetic and functional alterations.
 - ✓ Radiation therapy.
 - ✓ Systemic treatments: chemotherapy, hormone therapy, immunotherapy, etc.

On the socio-occupational and economic level

- Work-related:
 - ✓ In cancer patients, the occupational problems are many and range from loss of the employment contract to no possibility of continuing active employment within the extend of their possibilities.
 - ✓ In the case of the family members, some family member may leave their job in order to be able to take care of the sick person without the possibility of returning to the workplace.
 - ✓ Hasty decision-making to request some type of economic benefit may later detriment both the sick person and the members of their family.
- Economic:
 - ✓ Being on leave from work always entails a decrease in the basic income. This may be accompanied by the different incentives which the patient might cease earning.
 - ✓ Transportation to and from the hospital over long periods of time, having to eat out, the need for private caregivers, etc., increases the household budget expenses.

- ✓ In the case of patients from outside the province or from other towns, the expenses are overwhelming for the family budget, they being forced to seek economic aid by way of loans, etc.
- ✓ On the other hand, the medication which is administered is often very costly.
- ✓ There are a number of expenses which the patient must face as a result of the iatrogenics of the treatments: orthopedic apparatuses, prostheses, dentures, special undergarments, etc.
- Social:
 - ✓ The stigma of the disease, the change in physical appearance, the possible change in disposition or mood, not being able to enjoy the leisure-time activities like before, etc. may give rise to situations which may range from a lessening of social relations to isolation.
 - ✓ Some patients suffer a certain isolation on the part of the environment (often with the mistaken intention of not making them suffer), propitiating the loss of their role as a person and their active, useful role in society.
 - ✓ The hospital admission cycles are usually periods of time lending themselves little to amusement, thus involving making the person admitted even more indisposed .
- Family:
 - ✓ The current family structure (with fewer members or family members being geographically spread far apart) make it difficult to be able to carry out care and support tasks for the sick person within the family context.
 - ✓ The case may arise in which the sick person is, in turn, responsible for the care of other vulnerable members of the family (elderly, handicapped, small children, etc.)
 - ✓ Another problem is the self-abandonment of the caregivers. Some neglect their own personal, health and family needs, focusing exclusively on caring for the sick person.

- ✓ The disorientation and the impact caused by this disease may often give rise to situations of discord and misunderstanding among family members which may wind up causing situations of neglect.

3.5.5 Actions

General actions

- Favor carrying out awareness and educational programs for patients, the healthy population, healthcare personnel, the media and management personnel affording the possibility of demystifying cancer and modifying cancer-related negative attitudes and values.
- Promote the creation of psychooncology teams and further strengthen those currently in existence, where needs currently met to only a small degree or poorly met, as widely-varied as follows, may be covered:
 - ✓ Reinforce incomplete information or information misinterpreted by patients and family members with regard to this disease, its evolution and its treatment, facilitating the proper comprehension of the information.
 - ✓ Further strengthen, in patients and family members, appropriate, health strategies for dealing with this disease, the treatments, the professionals, the system as an organization, etc.
 - ✓ Detect, evaluate and, wherever applicable, approach possible responses with present or future psychopathological potential.
 - ✓ Help to positively focus and solve the emotional and personal problems which arise throughout the evolution of the process secondary to the disease and the care thereof.
 - ✓ Counseling as to patterns of organization and functioning of the patient's environment, load-sharing, prevention of codependency, etc.
 - ✓ Inform patients and family members as to the rights to which they have recourse in case of a situation of possible conflict arising, attempting to help to seek positive solutions whenever possible.

- Improve the communicating skills and abilities of all of the healthcare professionals who are working with the cancer patient and the patient's family, teaching communicating techniques to optimize the care to be provided to them and prevent and identify any professional burnout syndrome, by means of:
 - ✓ Training programs of basic psychological aspects, communicating skills and handling difficult situations.
 - ✓ Developing of clinical guides and protocols for referral and taking action.
 - ✓ Facilitating interprofessional meetings and exchanges within and outside of the team for this purpose.
- Reinforce the social worker figure such that, through the functional departments or by means of risk situation indicators, the right actions may be taken in each situation as a measure for prevention further complications.
 - ✓ Promote a suitable coordination between the services and resources.
 - ✓ Further strengthen the home volunteering for patient and family support.

Specific actions

At the psychological level

- Foster there being a physician responsible for patients in each stage of the disease and avoid changes in the team of professionals providing the care.
- Promote appropriate communications between the patients and their families and the physician responsible for the patient's treatment and with the rest of the team providing the patient's care.
- Improve the information furnished to patients and their families.
- Guarantee, whenever necessary, the access to psychological care for patients and family members from the start of and throughout the entire process of the disease, including for the family following the patient's death.

- Promote measures of a preventive type in the psychological care for both the patients and their families.
- Treat the psychopathological symptomology.
- Create an awareness among the healthcare professionals and the institutions so that they will consider subjective and individualized quality of life to be top-priority objectives in their actions.
- Optimize and support the natural support networks (family and friends), as well as the use of artificial networks created for this purpose (social support groups, self-help groups, volunteers, etc.)
- Furnish the professionals with the means and incentives necessary for a greater mastery of the communicating techniques (attention to the differences in the language used by the physician and by the patient), information and handling of conflictive situations, training on desirable behaviors in characteristic situations (small children, the elderly, the physically or mentally handicapped, cultural and racial problems) through the availability of continuing training and recycling activities.
- Prevent and reduce the occupational stress of the healthcare professionals by providing them with access to support, orientation, supervision, relief, recycling systems and the acquisition of proper interpersonal skills.
- Further strengthen the use of resources of a spiritual type in those patients for whom religiousness plays a major role in their lives.

At the physical level

- Facilitate the treatments and the implementation thereof under the best conditions of quality and comfort:
 - ✓ Improve accessibility.
 - ✓ Shorten the waiting times for conducting tests and notifying the results and for starting the treatments.
 - ✓ Suitably adapt rooms and spaces.

- ✓ Foster out-patient treatments.
- ✓ Develop behaviors and attitudes on the part of the healthcare personnel which will be pleasant for the patients, etc.
- ✓ Facilitate palliative and support treatments proportionately throughout the entire process and not solely in the terminal stages.

Surgical treatment

- Increase the possibilities of conservative treatment and reconstruction in all of the cases in which it be possible:
 - ✓ Conservation rather than amputation: breast, colorectal, laryngeal, limb, prostate cancers, etc.
 - ✓ Reconstruction: grafts with microvascular anastomosis techniques
 - Muscle transposition
 - Lysis of muscular contractures
 - Neo-bladders, etc.
 - ✓ Creation of rehabilitation units:
 - Physical therapy, phoniatry, lymphedema, etc.

Radiation therapy treatment

The toxicity of the treatment depends mainly on the tumor localization, the total doses, the fractioning of the dose and the technical equipment (apparatuses, planning, intensity modulation, etc.), it therefore being fundamental:

- To adapt the technical equipment of the radiation therapy departments.
- To foster validated support treatments during and following the treatment.

Chemotherapy treatment

Suitable support treatments currently exist which help to prevent and/or treat many of the side-effects of this treatment, it therefore being highly important:

- To foster and increase the possibilities of validated support treatments during and following the treatment.
- To prevent unnecessary iatrogenias (extravasation, tissular necrosis, etc.)

At the socio-occupational and economic level

At the work-related level

- Provide orientation and counseling concerning the occupational prospects from which the patients and their families may benefit.
- Help in the decision-making and management of steps taken for occupation-related purposes.
- Provide orientation as to the prospects of help for the purpose of avoiding losing out on the studies in which both the patient as well as the family member taking care thereof are involved.

At the economic level

- Orientation concerning the rights of the patients and their families. Advise them as to the Government aid, the specific NGO resources, as well as the resources available in each Autonomous Community.
- Evaluate the economic needs jointly with the patients and their families in order to be able to manage and take the steps to process the aid from which they are entitled.
- Facilitate the necessary social and material resources to the family in order for them to be able to care for the patient properly and fittingly.

At the social level

- Provide orientation to the patients and their families concerning the social conditioning factors of this disease, helping them to distinguish between what is beneficial for them and what may be in their detriment.
- Encourage the patients and their families to normalize their relations to the extent possible.
- Foster the setting up of networks which will favor the relations either among patients or among patients and their families, etc.
- Provide orientation concerning the different leisure-time groups and associations from which they may benefit.
- Incorporate, to the extent possible, professionals who will round out the care: occupational therapists, art therapists, etc.
- Facilitate access to the resources and foster the setup and functional organization of social support networks.
- Further strengthen home volunteering within the NGO's (Spanish Cancer League, Patients' Associations, etc).

At the family level

- Provide counseling and manage the aid necessary to ensure that the care which the patients require will be covered.
- Facilitate human resources, such as volunteers, for accompanying those persons who avail of little family support.
- Coordinate the resources necessary for alleviating the family responsibilities of the sick persons and/or their caregivers.
- Foster the caregivers and their families taking care of their selves, by counseling them as to the benefit thereof and fostering their assertiveness as a proper ability for requesting help.

- Carry out family mediation processes in view of crisis situations caused by discord or lack of organization in the care being provided.
- Foster the self-esteem of the caregivers and of the family group by identifying with them their own abilities and resources, as well as acknowledging the effort being invested in their endeavor.

3.5.6 Examples of good practices

PSYCHOONCOLOGY DEPARTMENT. CATALONIAN INSTITUTE OF ONCOLOGY (ICO) 1999-2003

Psychooncology Department for psychological care in oncology

- Psychological evaluation, diagnosis and treatment of patients and family members.
- Individual or group psychotherapy care.
- Consultant and participant in the clinical sessions of the oncology services (medical oncology, radiation therapy oncology, clinical hematology, palliative care and genetic counseling department).
- Evaluation and follow-up of the patients and family members undergoing genetic studies.
- Psychological guidance and care for the institution professionals.
- Collaboration with the psychoeducational programs offered for patients and family members (information on the emotional aspects in relation to the diagnosis of cancer and its treatments, relaxation workshops).

This care is provided on an out-patient and in-patient basis.

Number of new patients seen

Outpatient consultations

- 1999: 194
- 2000: 206
- 2001: 345
- 2002: 319
- 2003 forecast: 350
- Interconsultations (hospitalized): 898 (1999-2002)

REHABILITATION AND PHYSICAL THERAPY DEPARTMENT
VALENCIAN INSTITUTE OF ONCOLOGY FOUNDATION
1999-2003

- Physical rehabilitation department for cancer and cancer treatment side-effects.
 - ✓ Prevention and treatment of lymphedema
 - ✓ Treatment of post-radiation therapy sequelae
 - ✓ Post-surgery orthopedic rehabilitation
 - ✓ Neurological rehabilitation
 - ✓ Rehabilitation of painful bone-muscle syndromes
 - ✓ Respiratory physical therapy
 - ✓ Long-term bedridden patients

- This care is provided on an out-patient and/or home care basis.

- Number of new patients seen:
 - ✓ 1999: 63
 - ✓ 2000: 154
 - ✓ 2001: 240
 - ✓ 2002: 289
 - ✓ 2003 forecast: 340

3.7 PALLIATIVE CARE

3.6.1 Background information

The advances and terminal stage of cancer cause intense suffering for the patients and families and also for the healthcare professionals responsible for their care. There is a great need and demand for care related to the following profile (Guide to Palliative Care Quality Criteria, 2002):

- Advanced, incurable, progressive disease
- Very low responsiveness to the anti-tumor treatment
- Fluctuating evolution and frequent crises of need
- Intense emotional and family impact
- Repercussions on the caregiving structure
- Limited life expectancy prognosis

For different reasons, one of the most important of which is a small degree of training in palliative medicine and the many repercussions on the individual being taken into consideration to an insufficient degree in current medicine, the standard care received by these patients is often inadequate and insufficient, with the consequent unnecessary suffering on the part of many (Von Rően *et al.*, 1993; Cleeland *et al.*, 1994; Addington-Hill and McCarthy, 1995; SUPPORT, 1995; Gómez, 1998; Pascual, 1999). In view of this situation, there is a widespread demand for affordable, good quality human being-oriented care which will afford the possibility of life and death with dignity (Singer *et al.*, 1999). Palliative care is intended to offer, from a biopsychosocial dynamic, a professional, scientific and human response to the needs of the patients and their family members.

The WHO (Sepúlveda *et al.*, 2002) defines palliative care as a “an approach that improves the quality of life of patients and their families facing the problem associated

with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual". Palliative care:

- provides relief from pain and other distressing symptoms
- affirms life and regards dying as a normal process
- intends neither to hasten or postpone death
- integrates the psychological and spiritual aspects of patient care
- offers a support system to help patients live as actively as possible until death
- offers a support system to help the family cope during the patient's illness and in their own bereavement
- uses a team approach to address the needs of patients and their families, including bereavement counseling, if indicated
- will enhance quality of life, and may also positively influence the course of an illness
- is applicable early in the course of illness, in conjunction with other therapies that are intended to prolong life, such as chemotherapy or radiation therapy, and includes those investigations needed to *better* understand and *manage* distressing clinical complications.

This integral model of palliative care, based originally on the teachings of the hospice movement, has shown itself to be effective and efficient, being the treatment alternative of choice in the advanced, terminal situation (Hearn and Higginson, 1998; Gómez Batiste, 2001; Gómez Batiste *et al*, 2002). A modern palliative care concept must take in the transversality of the treatment measures throughout the evolution (Fig. 3.3) of the disease, guaranteeing care continuity (ASCO, 1998; Ahmedzai and Walsh, 2000; Spanish Society for Palliative Care and Family and Community Medicine Societies (SECPAL-SMFYC) Consensus Document, 2001; Valentin, 2003). Over the past few years, different publications have stressed the responsibility of the oncology

teams in starting palliative treatment guidance and in the subsequent coordination of the different care levels (Cherny and Catane, 1996; Catane, 1999; González Barón, 1996; Maltoni and Amadori, 2001).

All patients have a right to palliative care in an advanced, terminal situation (National Palliative Care Plan, 2001). The guaranteeing of this right is a fundamental activity in cancer treatment and therefore a responsibility of the National Health Care System. In keeping with the latest developments in modern bioethics and the recent rules of law (Patient Self-reliance Law 42/2002), the all palliative interventions must revolve around the patient proper, who is, a priori, a self-reliant subject capable of making decisions concerning their future.

FIG. 3.3 INTEGRAL MODEL OF PALLIATIVE CARE PROPOSED BY THE WORLD HEALTH ORGANIZATION



Source: WHO, 1990.

This care model must be of the following characteristics (National Palliative Care Plan, 2001); integral (covering all of the physical, psychological, social and spiritual needs), integrated into the health system, divided into sectors by healthcare areas, coordinated among the specialized and primary care levels and services, open to the coordination with social resources and comprised of interdisciplinary teams.

The discussion concerning the service portfolio and the coordination must be based on the patient's needs. Each healthcare area should identify and further strengthen their palliative care resources. An ideal model would take in, in conjunction with a high-level competency of the specialized and primary care professionals, the presence of specific palliative care teams in hospitals providing acute care, in centers of a sociosanitary profile and in home care.

3.6.2 Standards

All cancer patients must receive palliative care during the advanced and terminal stages of the disease at any level of care, including the intervention of specific palliative care teams in view of complex situations.

The families and/or caregivers are to receive the palliative care in keeping with their needs.

3.6.3 Objectives

- Identify the needs of patients and families and set out an interdisciplinary care plan for all patients in an advanced, terminal situation at any level of care.
- Ensure the agreed, coordinated response among the different levels of care of each healthcare area, including specific palliative care on an in-patient and home care basis.
- Carry out continuing palliative care quality improvement actions.
- Improve the training in palliative care on the part of the healthcare professionals.
- Further strengthen research in palliative care.

3.6.4 Critical points

- Problems in recognizing and identifying the terminal stage: feeling of failure, predominantly cure-oriented medicine, very little emphases on controlling symptoms and quality of life.
- Highly limited habit of interdisciplinary work.
- Inadequate communication. False expectations on the part of the patients.
- Need of social workers and mental health professionals on the teams.

- Excessive care pressure (Benítez *et al.*, 1999).
- Lack of availability at home of some absolutely essential drugs (i.e. Midazolam) and consumables (i.e. infusers for administering subcutaneous medication) exclusively for hospital use.
- Organizational problems. One of which is the fragmentation of the care with insufficient coordination among levels of care, the lack of knowledge of the care models, the small number of integrated palliative care programs, the lack of availability of specific services and the lack of palliative care beds.
- Professional burnout of the teams. Lack of recognition of the palliative care occupational category.
- Training deficiencies at the basic, intermediate and advanced level (SECPAL, 1999).
- Small amount of evidence and clinical practice guides in palliative medicine.
- Deficit of research in palliative medicine.

3.6.5 Actions

For Objective No. 1

- At the point in time of including a patient in a palliative care program at any level of care, the healthcare professionals shall record on the clinical record a list of their physical symptoms, emotional state, social and spiritual needs, information and communication; the family needs, including bereavement care and the interdisciplinary treatment plan.

For Objective No. 2

- The Health Administration shall describe the care process, including the identification of palliative care resources and setups and the integration thereof by health areas. The teams responsible for the specific home care and hospital care programs shall be defined by health area(s).

- The management of each hospital shall establish an expeditious emergency care circuit and, wherever applicable, hospitalization of the subsidiary palliative care patients.
- The management of each hospital shall assure the availability of beds devoted specifically to palliative care at general hospitals and sociosanitary centers, respecting the privacy and private life of patients and companions.

The following are proposed as other measures fostering the integration of levels:

- Definition of the figure of a coordinator responsible for palliative care on the primary care teams.
- Setting up expert palliative care devices and 24-hour phone interconsultation.
- Setting up an interdisciplinary palliative care commission in each health district, the main missions of which shall be to guarantee care continuity and review the care processes.

For Objective No. 3

- Promoting that a standing study committee be set up within the National Palliative Care Plan among the scientific societies involved to the greatest extent for the preparation of rules and guidelines for carrying out palliative care programs, clinical practice guides and protocols.
- Develop healthcare professional self-help strategies.
- Foster the participation of the volunteer force and the coordination with social support structures.

For Objective No. 4

- It is recommended that the academic authorities include palliative care in the undergraduate curriculum.

- The specific oncology teams and services, with the support of scientific societies and professional organization, shall carry out basic training measures in each health area.
- The national commissions of the specialties involved (i.e. medical oncology, radiation therapy oncology, hematology, family medicine, internal medicine) shall promote residencies of MIR specialists in training in palliative care units.
- It is proposed to the National Specialization Council that the area of specific training in palliative care be promoted.

For Objective No. 5

- It is recommended that research projects on palliative care be included among the strategy lines of the State an Autonomous Community research agencies.
- The health authorities shall promote lines of research which will evaluate the impact of the measures taken based on the plan on the effectiveness and efficiency of palliative care having been gotten under way and on patient and family member satisfaction.

3.6.6 Examples of good practices

EDMONTON REGIONAL PALLIATIVE CARE PROGRAM

This is an excellent integrated palliative care model with coordination among an institute of oncology, an acute palliative care department, centers of a sociosanitary profile and home care, with the active involvement of the primary care teams. In this program, clinical evaluation tools used in the modern palliative care programs have been developed. It also includes reports on the care-providing, education and research activity which may serve as a model for getting under way and describing the activity of palliative care programs.

Source: *www.palliative.org*

MODEL PATIENT AND FAMILY CARE GUIDE CANADIAN PALLIATIVE CARE ASSOCIATION

This guide summarizes a long process of broad-ranging national consensus among health authorities, scientific societies, professional organizations, management officials and educators. It includes agreements concerning definitions of commonly-employed terms, values and principles and rules of practice to guide patient and family care. A description is provided with domains linked to this disease and to bereavement: management of the disease, physical domain, psychological domain, social domain, spiritual domain, practical domain, end-of-life and bereavement care. The basic stages during any treatment encounter applicable to each one of these domains; evaluation, information, decision-making, care planning, provision of care and confirmation are also defined.

Source: *www.cPCA.net*

A GUIDE TO PALLIATIVE CARE QUALITY CRITERIA. SPAIN

The Spanish Society for Palliative Care proposes to set out and reach a consensus concerning the main quality criteria and good practices in palliative care. A total of 106 quality criteria are defined, grouped into definitions, structure, organization and processes, which mark a commitment to professional care quality with the hope of being of use to the professionals as a basis for innovation and the further development of this area of knowledge.

Source: Gómez-Batiste X, De la Mata I, Fernández M, Ferrer J, García E, Novellas A, Pascual A, Picaza J, Sánchez M, Sanmartín J, Sastre P, Suñol R, *Guía de criterios de calidad en cuidados paliativos*. SECPAL, FAD. Ministry of Health and Consumer Affairs, 2002.

CONTINUING CARE IN AN INTEGRAL PALLIATIVE PROGRAM: THE EXPERIENCE OF THE GRAND CANARY ISLAND HOSPITAL. DR. NEGRÍN.

A round-the-clock telephone service, with a physician on call, has, among other advantages, that of patently reduce the use of the emergency service on the part of the patients in an advanced, terminal situation, formerly regular customers. A good control of symptoms, psychosocial support for patients and family members and a round-the-clock telephone service leads to patients rarely having to come in to this department. This aspect may have had a major bearing on the number of emergency cases seen at the hospital having dropped by 21,743 emergencies less (27.95%) in five years. The annual average is 4,348 fewer emergencies. Those cost of providing care for an emergency was established at that time at 100 euros, which would therefore mean savings of 435,000 euros/year, in addition to the main objective, which is the enhanced quality of life of patients and their family members.

The physician on call can be called from the hospitalization floor or from any other floor in the hospital, but may also be called directly from the homes of the patients for which care is being provided through the home care program. Most of the times, the problem can be solved over the phone (adjusting a dose, dispelling a doubt, emotional support, etc.) without any need of mobilizing the patient or other healthcare resources. When the patient must be hospitalized, this is done directly from their home to the hospital floor without even going through the emergency department.

Source: Gómez Sancho M., “Sistemas integrales de alta cobertura; la experiencia de Las Palmas de Gran Canaria (España)”, in Gómez Sancho M (ed.), *Medicina Paliativa en la Cultura Latina*. Madrid: Arán, 1999, 1243-1256.

FAMILY MEMBER CAREGIVER CARE SERVICE IN THE AUTONOMOUS COMMUNITY OF CASTILE AND LEON

Included in the Castile and Leon Regional Health Service primary care service portfolio in 2003. This service was gotten under way with the general objective of improving the quality of life related to the health of the family member caregivers and wit other specific objectives, such as heightening the caregiving skills, reducing the incidence and prevalence of the caregiver syndrome, fostering self-help in a group dynamic and promoting community involvement.

The information on the pilot experience of this service, activities included therein, indicators, minimum technical standards... may be consulted at: Servicio de Coordinación Sociosanitaria. Dirección General de Planificación y Ordenación. Consejería de Sanidad de Castilla y León.

WHO PALLIATIVE CARE PILOT PROGRAM IN CATALONIA

In 1989, an official program was prepared for providing palliative care in Catalonia, based on the public health program principles and with the objectives of coverage, equity, quality and reference. The measures consisted of the implementation of specific resources (with an overall and sectorized concept), training, accessibility of opioids and the quality legislation and standards, with proposed follow-up indicators.

The results in 2001 showed 133 teams (60 home care teams, 52 Departments – nearly 550 beds – and 31 hospital teams) with a coverage nearing 70% for cancer patients, a rate of 84 beds/million inhabitants, over 95% geographical accessibility, diversity of resource with regard to its location, and a noticeable increase in the use of opioids (3.5 kg/million inhabitants in 1989 and over 17 in 1998).

The importance of this experience lies in its being an official World Health Organization program which has demonstrated results at 10 years.

Source: Gómez-Batiste X, Porta J, Tuca A *et al.*, Spain: The WHO Demonstration Project on Palliative Care Implementation in Catalonia: results at 10 years. *J. Pain Symptom Manage*, 2002 24 2), 239-44.

3.7 INFORMATION SYSTEMS

3.7.1 Background information

The currently-existing information on cancer is related mainly to different studies and analyses concerning:

1. Risk factors
2. Mortality
3. Incidence and estimated prevalence
4. Survival
5. Hospital morbidity
6. Care and clinical handling
7. Early detection program coverages
8. Care-providing resources

As a point of reference, we have the following integral intervention cancer plans or programs under way in Spain:

- 2002-2006 Integral oncology plan of Andalusia
- 2002-2004 Regional Cancer Strategy in Castile and Leon
- 2001-2004 Master oncology plan in Catalonia
- 2002-2005 Galicia oncology plan
- 2001 Navarra oncology plan
- 2002-2006 Community of Valencia oncology plan

No nationwide information however exists for certain aspects which is representative, in turn, for each Autonomous Community. Nor are there a sufficient number of systematized studies relating actions and outcomes in an overall manner. In some cases, the existing information is also not sufficiently homogenized or readily accessible, the usefulness of certain data therefore being limited.

In short, the information is diverse and disperse, there being no true cancer information system, which must be built at the same time as the NHS Cancer Strategy is being carried out.

Different sources of information which may be used in general terms for the purpose of making the best use of that which does exist are nevertheless attached at the end of this chapter, although it shall be necessary to take up new data collection systems and improve the existing ones.

On the international plane, the current reference points are the recommendations of the III Europe Against Cancer Action Plan for 1996-1997 at the European Union level. Similarly, when establishing indicators, there is the reference point of those included in the EUROCHIP (European Cancer Health Indicator Project) also at the European Union level.

There are, however, very few references in general regarding specific indicators used in the plans for action against cancer, whether from the Autonomous Communities or from other countries. In most cases, the specific indicators for their measured are not explicitly stated and, in others, the existing indicators are mainly linked to highly specific operative follow-up of getting the Cancer Strategy under way.

Based on all of the above, it will be necessary to take up the information system of this NHS Cancer Strategy in several phases. First, draft a starting list of those indicators which are considered top-priority which comprise the proposal set out in this chapter. Next, given the current complexity involved in implementing some of these indicators, the processing of specifically defining these indicators and the strategies for obtaining them must then be taken up. Lastly, analyze the advisability of introducing new indicators as the registry systems progress, probably along with expanding in the use of computerized tools which will simplify data collection.

3.7.2 Standards

The NHS Cancer Strategy information system shall evaluate its impact on the health of the population and shall monitor the degree to which the objectives set are achieved.

3.7.3 Objectives

- Assess whether the Cancer Strategy as a whole is effective for achieving its objectives.
- Evaluated each one of the major areas of intervention included under the Cancer Strategy.
- Orient the implementation of corrective measures in the event that are actions do not meet with the anticipated results.
- Set the bases for the generation of an integrated information system which will include the standardization of the anatomopathological reports.

3.7.4 Critical points

The information system designed must also resolve the critical points which have been identified as top-priority at this point in time related to lacks and problems of availability of information, some of which may have a direct bearing on the possibility of obtaining the indicators proposed at a further point herein.

The main points which have been identified as being critical are as follows:

- The currently-existing population-based cancer registries, which make it possible to ascertain essential aspects of this health problem, such as those related to the magnitude of the problem and its evolution, the spatial distribution of the incidence and survival or the most specific clinical evaluation are not sufficiently endowed, generating delays and lessening possibilities of fully using this information. Additionally, their territorial coverage is partial, it not being possible to know all of these aspects in different geographical areas. Even the complete Autonomous Community registries have shortcomings, it being possible to additionally identify geographic areas which, due to their environmental situation, would require a population-based cancer registry.
- Access is not available to the information provided by the National Death Index, which includes the list of deceased individuals, which may facilitate obtaining the cancer survival indicators.

- Access is not available systematically through official channels to the individualized cause of death information from the health system.
- There is no clear, accessible information regarding the occupational exposure to carcinogenic substances or, in general, to environmental exposure data.
- No systematic data is available affording the possibility of relating the survival in the different types of cancer to the different types of clinical procedures and interventions employed.
- There is no integration of the data collection systems currently-existing within the different care-providing scopes, nor among Administrations which are involved in this problem. All this means a major loss of potentiality when using this data and lead to the resulting wasting of efforts due, in part, to their not being standardized.
- There is a deficit in the recording of data related to the outpatient visits at the hospital and with primary care, which causes problems in recording those cancers which do not require admission to hospital for their diagnosis and treatment.
- There is not sufficient information on the currently-existing hospital cancer registries either from the standpoint of the degree to which they are widespread or due to the degrees to which the data collection criteria and rules are standardized.

3.7.5 Actions

- Promote the improvement and expansion of the population-based cancer registries so that they will afford the possibility of covering, with sufficient quality and representativity, those aspects and territories which are currently showing deficits.
- Get the mechanisms under way to make it possible to access the data provided by the National Death Index.
- Promote the development of the legal mechanism to afford the health sector with the possibility of accessing the individualized causes of death information.

- Promote the creation and improvement of registry systems for environmental exposures to carcinogenic substances, placing special attention on those within an occupational scope.
- Make a current situation diagnostic of the hospital cancer registries in order to be able to work on a proposal, based on that knowledge, as to what basic data must be common and be standardized.
- Undertake, based on a consensus, the design and implementation of the coded collection of diagnosis and treatment-related data in non-hospitalized cancer patients (at the level of external hospital consultations and outpatient consultations) so as to round out the information from the in-patients.
- Facilitate the SNOMED-CT Systemized Nomenclature of Medicine and promote its use as an anatomopathological diagnosis classification and coding system at all hospitals, as well in the pathological anatomy laboratories located outside of hospitals.
- Further strengthen the mechanism affording the possibility of interrelating and integration information so that this information may be shared and put into practice by all. On one hand, under the criteria of the complexity of the data collected and, on the other, so that it will make comparability possible in those cases in which no common criteria exist.
- Foster that, when developing the local data collection systems, compatibility both of technical and technological criteria be taken into account in the clinical computerization process of the different scopes of care.

Levels of evaluation and levels of analysis

Two levels have been established for the design and construction of the follow-up and evaluation indicators of the NHS Cancer Strategy.

The first level has to do with the follow-up and evaluation criteria and procedures making it possible to ascertain whether the Cancer Strategy as a whole is effective for achieving its objectives.

The second level essentially has to do with the development of each one of the areas of intervention proposed in the Cancer Strategy as a result of including unique actions possessing their own references, procedures and methodological techniques according to the specific characteristics thereof.

On the other hand, when using and analyzing the information, the following shall be taken into account:

NHS level: A small number of *indicators*, taken from the seven areas of intervention and revolving around the evaluation of the carrying out of the Cancer Strategy (extension, coverage and some intermediate results) must be obtained, analyzed and interpreted and, on a medium-range basis, in the analysis of the cancer morbimortality trend. It is at this level where there is probably a sufficient amount of data to demonstrate trends within a reasonable length of time.

Autonomous Community level: In each healthcare service, it shall be necessary to know the functioning of the Cancer Strategy from a more detailed perspective, through a wider range of *indicators* which place a value on each one of the seven areas. Many of these indicators shall be related to the resources earmarked and the processes gotten under way, as well as to determining mainly intermediate result measurements.

The center level and professional level are not included here in general as a result of considering the even more detailed monitoring of the care-providing process that this level would add as not being pertinent to be evaluated by the Cancer Strategy.

3.7.6 Indicators

When setting out the specific indicators for following-up on the Cancer Strategy, the first task is that of clearly setting the bounds of what can be measured immediately and what will require new data collection systems. However, a glance through the different critical points reveals the difficulties involved in this task. The current diversity of sources with possibly non-homogeneous criteria, the need of harmonizing the information and using standardized data and the fact of having to take up new registries and used make it necessary for a careful, detailed definition of the terms used to be made for constructing each indicator.

It must be taken into account that those criteria which are already standardized at the European level (including in the EUROCHIP) will have to be used for the definitions of the corresponding indicators. This will assure the comparability of these aspects with our countries in our environment and globally with Europe. In all other cases, it will be necessary to also standardize the informational at the nationwide level.

For all these purposes, It is therefore indispensable to set out, prior to developing the information system proposed in this Cancer Strategy, one sole definition of each numerator and denominator with which the indicators are to be constructed and to determine the planned levels of breakdown. Along with this, it is important to clarify the sources from which information is to be obtained in each case and the timeframes, which shall be fixed in terms of the availability of obtaining the data and/or of the time frames within which it is anticipated that the effect intended to be measured will take to manifest itself. The standardization of the pathological anatomy reports shall also be approached.

The items intended to be evaluated, which are listed in following, entail a small example of the wide range of indicators and aspects subject to being evaluated which the different working groups have set out. Some have not been included in the end due to major feasibility-related problems, and others as a result of not being considered to from part of a follow-up of a local scope, linked to the evaluation of care-providing process quality criteria, which comes more under the authority of the local healthcare and/or management scopes. Some process indicators are nevertheless included which may be of use to generally monitoring the degree of progress in implementing the Cancer Strategy.

However, it is equally as important as precisely determining the indicators to be ensured that the data necessary for their construction is available, and that this data meets the sufficient level of quality. Making it possible to evaluate the care-providing process is inseparably linked to the proper registry of the medical records. Despite this seemingly being obvious, this aspect should be stressed, given that solely by way of heightening the quality of the medical records themselves will it be possible to avail of the data necessary for many indicators, whether they be evaluated locally or be included in those proposed herein.

	INDICATORS	SOURCES
Measurement of the impact	Cancer mortality, overall and by types of cancer and by gender, standardized by age*.	Spanish National Institute of Statistics death statistics.
	Potential years of life lost, by tumor groups, by age and by gender.	population-based cancer registries.
	Incidence rates, by tumor groups, by age groups and by gender*.	National Childhood Tumor Registry
	Observed and relative population-based survival rates at 1, 3 and 5 years (by tumor groups and gender)*.	National Death Index – Ministry of Health and Consumer Affairs.
Primary prevention “Reduce the prevalence of risk factors and the incidence of cancer by means of adopting health promotion and protection and cancer prevention measures.”	Smoking habit prevalence* and percentage having quit smoking.	National Health Survey/Health surveys of the Autonomous Communities.
	Prevalence of passive exposure to tobacco smoke*.	Spanish Ministry of Agriculture and Fisheries food consumption panel (National Nutrition and Food Survey-European Parliamentary Forum and Spanish National Institute of Statistics
	Alcohol consumption*.	
	Prevalence of overweight and obesity*.	National Drug Plan- Ministry of Health and Consumer Affairs
	Consumption of fruits and green leafy vegetables*.	Health barometer
	Degree of physical activity*.	Environmental information systems of the Autonomous Communities.
	Degree of knowledge by the population of risk factors and protective measures against the same (i.e. eating fiber, sunscreens and others).	State registry of emissions and source of pollution- EPER Spain . Spanish Ministry of the Environment.
	Degree of occupational exposure to carcinogens recognized by the IARC*.	
	Environmental exposure to PM10 and other substances*.	

	INDICATORS	SOURCES
<p>Early detection</p> <p>“The entire populations shall have access to specific early detection programs and interventions in accordance with their own characteristics which will afford the possibility of reducing their risk of morbid-mortality in relation to those tumors for which the efficiency and effectiveness thereof have been proven.”</p> <p>“No screening interventions of either an individual or population-based type shall be carried out if the efficiency thereof has not been scientifically proven.”</p>	<p>Percentage of asymptomatic women having had a mammogram within the past two years, by target population groups*.</p> <p>Percentage of women on whom a cytology has been performed within the past 3/5 years, by recommended age groups*.</p> <p>Participation rate (actual coverage) in said programs.</p> <p>Percentage of localized tumors of the total number of breast cancers detected*.</p> <p>Incidence of interval cancers*.</p> <p>Existence of active recruiting and organized follow-up programs of population groups at a high risk of colorectal cancer.</p>	<p>National Health Survey</p> <p>Early breast cancer detection programs of the Autonomous Communities.</p> <p>High-risk colorectal cancer group recruiting programs of the Autonomous Communities.</p>

	INDICATORS	SOURCES
<p>Adult care</p> <p>“Independently of their place of residence and age, all patients with a well-founded clinical suspicion of cancer must have access, within a reasonable timeframe, to a test at a healthcare center. confirming or ruling out this disease This clinical suspicion confirmation process must be carried out by means of priority circuits for accessing these diagnostic tests.”</p> <p>“In the case of a positive result confirming the suspicion, the subsequent diagnostic process must be carried out at a center which avails of the necessary laboratory, radiology and pathological anatomy resources and methods of sufficient capacity to guarantee that all patients diagnosed with cancer will avail of a quality extension study.”</p> <p>“All patients diagnosed with cancer must avail of an fully-planned, overall, personalized treatment plan.”</p> <p>“All patients diagnosed with those types of cancer which are infrequent or which require a highly complex therapeutic technique shall be referred to a hospital having specialists possessing sufficient experience to guarantee the best clinical outcomes.”</p> <p>“Those patients diagnosed with cancer must have access to quality cancer care,”</p> <p>“Those patients diagnosed with cancer must have access to the precise information for taking more active part, if they so desire, in the management of their own process.”</p>	<p>Map of highly-specialized services serving as a reference for the entire NHS.</p> <p>Number of radiation therapy, CAT, PET and MNR systems per million inhabitants*.</p> <p>Percentage of acute hospitals having tumor committees.</p> <p>Mean and range of the interval between the suspicion and the confirmed diagnosis.</p> <p>Mean and range of the interval between the confirmed diagnosis and the first treatment*.</p> <p>Percentage of patients having an overall treatment plan which is stated on their medical record.</p> <p>Survival by stage at point in time of the diagnosis.</p> <p>Total spending on antineoplastic drugs* (hospital and prescription consumption) adjusted by population.</p> <p>Percentage of conservative treatments and breast cancer and laryngeal cancer.</p> <p>Percentage of patients treated according to the best practices* (in certain selected tumors).</p>	<p>National Hospital Catalogue</p> <p>Statistics on Healthcare Establishments with In-patient regimen.</p> <p>Specific delay-related studies.</p> <p>Hospital tumor registries.</p> <p>Specific studies on medical records</p> <p>population-based cancer records</p> <p>Prescription drug consumption information system (IS)- Spanish Directorate General of Pharmacy and Health Products</p> <p>Hospital pharmacy information system (IS).</p> <p>MBDS.</p>

	INDICATORS	SOURCES
<p>Child and adolescent care</p> <p>“All children and adolescents diagnosed with cancer must be provided with complete, integral, multidisciplinary care and have access to the current national and international diagnosis and treatment protocols.”</p> <p>“The care of these children in multidisciplinary pediatric oncohematology departments which meet the International Society for Pediatric Oncology (SIOP) requirements set out in Table 3.4 must be guaranteed.”</p> <p>“Those children and adolescents cured of a cancer must be able to grow up to be adults leading a normal life, integrated into the society of their time. For this purpose, it is indispensable that psychosocial care be provided for these patients and their family members starting as of the point in time of the diagnosis.”</p>	<p>NHS reference map for childhood cancer care through pediatric oncohematology departments in accordance with set requirements.</p> <p>Mean and range of the interval between the suspicion and the confirmed diagnosis.</p> <p>Mean and range of the interval between the confirmed diagnosis and the first treatment*.</p> <p>Percentage of children provided with psychological care.</p> <p>Percentage of hospitals with pediatric oncohematology departments which have tumor banks.</p> <p>Percentage of pediatric oncohematology departments which send in information to the National Childhood Tumor Registry.</p>	<p>National Childhood Tumor Registry</p> <p>Population-based cancer registries</p> <p>Specific delay-related studies</p> <p>Specific studies on medical records</p>
<p>Quality of life</p> <p>“All patients diagnosed with cancer must have access to:</p> <ul style="list-style-type: none"> • control of the sequelae and side-effects of the treatments • psychological care • physical rehabilitation • adequate social, occupational and economic resources”. 	<p>Evaluation of cancer patient quality of life</p> <p>Percentage of patients provided with psychological support.</p> <p>Percentage of patients in which some adverse effect of the treatment has been notified.</p> <p>Percentage of patients with reparatory plastic surgery of those who have undergone radical surgery.</p>	<p>Specific studies on the quality of life of patients diagnosed with cancer within the last year, within the past three months,... (short and medium-range)</p> <p>Specific studies on medical records</p> <p>Permanent disability information system (IS) of the Autonomous Communities</p> <p>Pharmacosurveillance information system (IS). Spanish Drug and Health Product Agency.</p>

	INDICATORS	SOURCES
Palliative care “All cancer patients must receive palliative care during the advanced and terminal stages of the disease at any level of care..” “The families and/or caregivers are to receive the palliative care in keeping with their needs.” “All cancer patients must receive expert palliative care provided by specific palliative care teams in view of complex situations.”	Existence of a care program at the Autonomous Community level, in which the necessary palliative care-related organizational, functional and training aspects are included.	Autonomous Community reports Special studies on medical records
	Percentage of terminal cancer patients for which provided (actual coverage of the program) of the total number of terminal patients and of the total number of deaths due to cancer.	MBDS Pharmaceutical consumption information system (IS) – Spanish Directorate General of Pharmacy and Health Products.
	Percentage of patients on whose medical record there is a record of initial evaluation of needs of the patient and their family and interdisciplinary treatment plan.	Specific hospital pharmacy and primary care registry
	Percentage of patients undergoing palliative radiation therapy*.	
	Consumption of morphine in DDD (subsequently in DHD) in terminal patients*.	

	INDICATORS	SOURCES
<p>Research</p> <p>“Biomedical research is an activity necessary for the success of any strategy which proposed to improve the health of those citizens affected by cancer. The integration of research into clinical practice fosters a better quality of the health services and a better and faster-paced implementation of the scientific advances in disease prevention, diagnosis and treatment, as well as more highly ethical, efficient patient care”.</p> <p>“In all cases, the research quality standards may solely be guaranteed by means of the implementation of programs for the follow-up and periodical external evaluation of all of the research activities”.</p>	<p>For each line of basic research, clinical research and epidemiological or clinical-epidemiological research:</p> <ul style="list-style-type: none"> • Publications on cancer in international-level scientific journals. • Number of projects financed in national or international-level competitive processes (excluding clinical trials financed by the industry). • Total amount for projects in national and international-level competitive processes (not including clinical trials financed by the industry). • Number of projects, number of patients and investment in research in collaboration with the biotechnology or pharmaceutical industry. • Generation of patents (for the cases of basic and clinical research). 	<p>Databases, such as Medline and PubMed</p> <p>Public Health Research Fund – Ministry of Health and Consumer Affairs- Map of biomedical research in Spain.</p> <p>Esp@cenet</p> <p>Databases of the Spanish Patent and Trademark Office – Spanish Ministry of Science and Technology</p> <p>European Patent Office</p> <p>World Intellectual Property Organization</p>

* Indicators included in Eurochip

Repertory of currently-existing sources of cancer information

Death statistics: Mortality data by causes, total and broken down by gender and age groups. Spanish National Institute of Statistics.

Population-based cancer records: Systematic information on all of the cases of cancer which have arisen within a structurally and geographically-defined population.

National Childhood Tumor Registry: Centralized, hospital-based registry on cancer patients under 15 years of age.

Hospital tumor registries: Information on all of the cases of cancer for which care has been provided at a certain hospital.

National Health Survey: Information on risk factors which have a bearing on cancer. Ministry of Health and Consumer Affairs.

Health barometer: Information on the citizens' opinion concerning different aspects related to the health system and their health. Ministry of Health and Consumer Affairs.

Autonomous Community early breast cancer detection programs: Information on different aspects related to this early detection. Autonomous Communities.

NHC- National Hospital Catalogue: Information on physical resources (mainly hospitals and "installed" high technology), by types of hospitals. Ministry of Health and Consumer Affairs.

Statistics on healthcare establishments with in-patient regimen: Data on "working" physical and human, hospital and outpatient clinic resources. Includes information on activity and expenditures of these centers. Ministry of Health and Consumer Affairs.

MBDS – Minimum basic data set: Systematic data on diagnosis at release from hospital, including procedures carried out. Ministry of Health and Consumer Affairs.

Pharmacosurveillance information system: Information on adverse effects of the medications by way of a specifically-organized notification system. Ministry of Health and Consumer Affairs.

Drug consumption information system: Information on what drugs, and what quantity and at what cost have been prescribed by means of an official medical prescription. Ministry of Health and Consumer Affairs.

National Death Index: Individualized information on deaths. Ministry of Health and Consumer Affairs.

Characteristics, contents and limitations of the listed sources

- **Mortality statistics**

The mortality statistics are extremely useful in evaluating the health condition of the population, in epidemiological surveillance and in healthcare planning. The proper study of these statistics affords the possibility of observing the trends and differences in the death by causes among different population groups, of evaluating different healthcare intervention programs, setting out hypotheses for biomedical and epidemiological research and earmarking and sharing out healthcare resources.

All deaths entail the completion of three documents: the death statistics bulletin, the medical death certificate and the questionnaire for the notification to the registry. These three documents are collected by the Civil Registry of the locality where the death occurs. The latter two of these three documents are kept on file at said Civil Registry. The first document is sent to the Provincial Office of the National Institute of Statistics, and it is based upon this document that the death statistics are prepared.

The death statistics bulletin includes information on the deceased person (date of birth, place of birth, gender, marital status, occupation, place of residence and date of death) and on the causes of death (direct, intermediate and initial or main cause, as well as other processes which contributed to the death). Currently, the main cause of death is coded in keeping with the tenth revision of the International Disease Classification (IDC).

The many applications of the mortality studies may be limited by the validity of the information obtained based on a person's death. As of 1983, the National Institute of Statistics has set up working agreements with the Autonomous Communities concerning the deaths which have occurred within their territorial bounds. Although the

spirit of these agreements responded mainly to the need of expediting the gathering of data at the beginning, specifically the tasks of coding the cause of death, these agreements are currently the main objective of improving the quality of the information.

- ***Cancer registries***

The cancer registries are the essential part of any rational control cancer. Their importance for epidemiological research, planning the evaluation of the services and the providing of care proper to the patients has meant a considerable development of the registries in the world.

A cancer registry can be defined as “the process of continuously collecting information systematically on the frequency and characteristics of the notifiable neoplasias for the purpose of helping to evaluate and control the impact of cancer on the community”.

A cancer registry can be gotten under way to cover different objectives, which conditions the existence of different types of registries and involves, in turn, differences in the data collection scope, in the sources used and in the amount or type of information collected.

The objective of a ***population-based cancer registry*** is to collect all of the cases of cancer which arise within a definite population, which is generally marked geographically by governmental limits. The population-based cancer registries are an epidemiological tool for measuring the frequency of cancer, its distribution among different population groups and the variations which take place in cancer incidence over the course of time. Similarly, these registries play an essential role in the evaluation of the effectiveness of preventive actions, specifically of the broad-scale early cancer detection programs. Additionally, this type of registries are the basis for the design of descriptive and analytical epidemiological studies, and have become one of the most valuable tools for researching etiological hypotheses and studies or risk factors and safeguarding factures which determine the variability of the distribution of cancer in the populations.

The advancement in the knowledge of the incidence of cancer in Spain is due to a number of population-based cancer registries having been put into operation one after the other which, as of the sixties, have been progressively implemented with provincial or autonomic coverage. These registries currently cover more than 25% of Spain's population, and their geographical distribution furnished valuable information on the variability of the incidence of cancer at the nationwide level.

In Spain, there are currently a total of 14 general population-based registries in full operation: Albacete, Asturias, Basque Country, Canary Islands, Cantabria, Cuenca, Girona, Granada, Mallorca, Murcia, Navarra, La Rioja, Tarragona and Zaragoza.

The population-based cancer registries have achieved a certain degree of homogeneity in Spain, as well as a major degree of consistency and quality, although some have been set up only recently.

The term *hospital-based cancer registry* is understood as being a information system which continuously, systematically and exhaustively collects a set of basic standardized data on the frequency and characteristics of a hospital's registrable cancers, regardless of the patients' geographical place of residence and the hospital services or departments which these patients have contacted. The hospital-based cancer registry is a indispensable informative tools for monitoring all of the cases of cancer diagnosed or treated at the hospital, serving all of the professionals and bodies involved in the care for the purpose of facilitating the evaluations tasks necessary for guaranteeing the standards and quality of this care.

In this regard, the hospital-based cancer registries are a necessary element for making all cancer patients' right to equal care of the best possible quality a reality, independently of the type of cancer they may have, the services responsible for their care, their place of residence or the referral channel through which they have finally come to the hospital in question. In turn, the results of the hospital-based cancer registries mean a resource for management, research and teaching. The hospital registry can be one of the sources of information of the population-based cancer registry.

The *National Childhood Tumor Registry* was created in 1980, as a result of the collaboration among the Oncology Section of the Spanish Pediatrics Association and the Institute for Documental and Historical Studies on Science (CSIC-University of Valencia). This is a hospital-based cancer registry which gathers information on patients

under 15 years of age. The objective of this Registry is to better the knowledge of the dimensions and characteristics of childhood cancer and of the survival of these patients, as well as to contribute to carrying out the clinical and epidemiological research, the prevention and the care.

- ***National Health Survey***

The Ministry of Health and Consumer Affairs first began Spain's National Health Survey in 1987, which was continued in 1993, 1995, 1997, 2001 and 2003. Except for those of 1995 and 1997, these surveys afford the possibility of breaking down the information at the Autonomous Community level.

Spain's National Health Survey is population-oriented research which makes it possible to obtain information as to how the population perceives their health condition and to relate declared morbidity, use of healthcare services and living habits to one another and to certain sociodemographic and geographic characteristics. Knowing the distribution of these variables facilitates recognizing needs and assigning healthcare resources.

Two questionnaire forms are used for gathering this information: one, oriented toward the childhood population (under 16 years of age), which is completed by the child's mother or father and which does not include lifestyle-related variables; the other, oriented toward the adult population, which those surveyed answer in their own name and which collects the information organized into four blocks: perceived morbidity, use of healthcare services, lifestyles and personal and sociodemographic characteristics.

The lifestyle-related information includes cancer risk factors, such as smoking, drinking alcohol, physical exercise and frequency with which certain foods are eaten; the personal characteristics gathered being self-stated height and weight, affording the possibility of calculating the body mass index.

- **Health barometer**

The health barometer is an opinion study which has been being conducted by the Ministry of Health and Consumer Affairs since 1993. This study affords the possibility of:

- Knowing what opinion citizens have of the public health services.
- Knowing what opinion citizens have of measures connected to health policy objectives.
- Knowing the actual penetration of informative campaigns.
- Obtaining information on the degree of knowledge or the attitudes of the citizens toward specific health problems.
- Re-evaluating and knowing the evolution of public opinion concerning aspects analyzed in the past.

The results of the study are obtained through the use of a structured questionnaire which is administered individually at the home of the person surveyed, independently of whether or not the person in question has used the public services, given that the survey is targeted on the population in general. This questionnaire is divided into two well-defined parts:

- A fixed part, which analyzes the aspects related to the degree of interest that healthcare raises in relation to other public policies, relative opinions of the functioning of the National Health System in general and of the public health services in particular, type of health insurance, opinion of the accessibility, how they are personally treated and the technical capacity of the public primary care, specialized care (consultations and hospitalization) and emergency care services, as well as knowledge and opinion of other aspects, such as waiting lists.

This fixed part also includes a set of classification variables of a sociodemographic nature, which make it possible to ascertain what influence factors such as gender, age, activity, educational level, income level or dwelling size have on the degree of satisfaction with the public health services.

- A variable part, the objective of which is to spot check other dimensions considered of interest, such as the opinion of measures taken or to be taken, the impact of informative campaigns, attitudes regarding different health-related aspects, etc.

- ***Early breast cancer detection programs***

Early breast cancer detection consists of conducting a relatively simple, acceptable test on a definite asymptomatic population group so as to afford the possibility of classifying each female as probably or improbably having cancer or at risk of getting this disease.

Since 1990, when the Navarra program was gotten under way, early breast cancer detection programs have progressively been implemented in all of the Autonomous Communities, the information systems of which include useful indicators for the evaluation of the NHS Cancer Strategy.

- ***National Hospital Catalogue***

The National Hospital Catalogue has its origins in the Hospital Law of July 21, 1962 and, with a few interruptions, has been being published annually since that time. This Catalogue is fed information from the Health Councils of each one of the Autonomous Communities and by the Ministry of Defense.

Its objective is to provide basic information on the hospitals devoted to specialized, continuing care of patients on an in-patient basis, the end purpose of which is the diagnosis and/or treatment of these in-patients, as well as the care provided on an out-patient basis.

This Catalogue includes information on the end purpose of the care provided, detailing under whose authority the hospital functions, the number of beds installed and the existence of teaching arrangements and accreditation, all on December 31 yearly.

- ***Statistics on healthcare establishments with in-patient regimen***

Statistics implemented by an Order issued by the Office of the President of the Government on May 18, 1973, published annually by the National Institute of Statistics

up to 1995 and by the Ministry of Health and Consumer Affairs since 1996. The Autonomous Communities, which gather the information through their Health Councils, collaborate in preparing these statistics.

The objectives intended to be met are: a) to furnish information on a yearly basis concerning the care-providing, economic and teaching activity of the hospitals, as well as concerning the staffing, capacity and economic regime under which the hospitalized patients are provided care b) to ascertain the number of hospitals devoted to each different end purpose regarding the care provided thereby and their under the authority of what institution they are legally operating d) to provide a series of economic data on the hospital sector in order to integrate this data into the national accounts.

As of 1972, the date to which the first monograph published is related, this statistic has undergone several subsequent modifications. The last reform was as a result of the changes made in the public health system, particularly the new specialized care organization, which unites the hospitals with the specialized medical centers operating under these hospitals.

- ***MBDS at release from hospital. Minimum basic data set***

This is an information system which gathers data from all of the hospital releases, although it has not as yet been implemented at 100% of the hospitals (however currently being implemented at 98% of the public acute care hospitals and at 30% of the private ones), and varying in the degree to which it is used (at public acute care hospitals, more than 98% of the releases are coded into the system). In both cases, both the number of participating hospitals and the degree to which the releases are exhaustively coded are progressively increasing.

This source also provides information on diagnosis and treatment procedures employed, which is a major added value on making it possible to evaluate inequities in the healthcare received.

- ***Pharmacosurveillance information system***

The National Pharmacosurveillance Network has a detection system in which, in a standardized manner and following protocols for this purpose, the healthcare professionals and the producers proper have to notify the Ministry of Health and

Consumer Affairs as to all those side-effects and adverse effects having arisen in patients which they consider to possibly be related to a certain medication.

- ***Pharmaceutical consumption information system***

The Ministry of Health and Consumer Affairs is responsible for integrating the information on medications consumed by way of prescriptions coming from all of the Autonomous Communities for the purpose of preparing the pharmaceutical invoice and ascertaining the terms of the pharmaceutical benefit.

This system includes quantitative and qualitative prescription data, providing possibilities including that of extracting information on the pharmaceutical specialties consumed, the active ingredients comprising these specialties and the therapeutic groups to which they pertain. This system has data on consumption, both in number of units (prescriptions and packages) as well as in monetary amounts, such that different indicators related to the prescribing of these medications may be obtained based on this system.

- ***National Death Index***

Created by Order of the Ministry of the Office of the President in 2000, this index is currently in the process of being gotten under way. This Index is considered as affording the possibility of serving as a valuable tool for aiding in obtaining survival indicators, as well as aiding in epidemiological research, on providing, as a supplement to other direct sources, the mortality data to the follow-up of specific cohorts.

This Index nevertheless entails the major limitation of not including the cause of death.

3.7.7 Examples of good practices

THE POPULATION-BASED REGISTRIES IN SPAIN

In Spain, there are 12 population-based registries, the quality of which has been approved by the International Cancer Research Agency (IARC/WHO), prior to their incidence-related data having been included in the successive editions of the series *Cancer Incidence in Five Continents* (1). Three registries – Albacete, Asturias, Basque Country, Canary Islands, Cuenca, Girona, Granada, Mallorca, Murcia, Navarra, Tarragona and Zaragoza – cover 27% of Spain's population. Specialized professionals work on these registries performing different tasks: the identification of cases which must be registered, classification and coding of neoplasias, the information processing and data analysis. Standardized working methods and procedures are employed, the strictest standards of confidentiality being employed, and all of the registries are registered with the Data Protection Agency.

In addition to preparing basic incidence statistics by type of cancer, by age and gender, special analyses have been made on many of them regarding geographical distribution and time-related trends.

All of these registries are integrated into the European Network of Cancer Registries (ENCR), with active participation in working groups and on the executive committee.

Several of these registries participate and/or have participated with their data in numerous international projects on etiological and survival research. Two of the most outstanding of these are: The *European Cancer Registry-based study of Survival and Cancer Patients* (EUROCARE), started in 1989 for the purpose of ascertaining the cancer survival in Europe and explaining the differences thereof, in which the registries of the Basque Country, Girona, Granada, Mallorca, Murcia, Navarra, and Tarragona take part. Apart from this, five registries – Asturias, Basque Country, Granada, Murcia and Navarra – participate in the *European Prospective Investigation into Cancer and Nutrition* (EPIC), a cohort study which is being conducted in 10 European countries for the main purpose of evaluating the diet and living habit factors related to cancer, in which a cohort of five hundred thousand individuals, 45,000 of whom are Spanish, is being followed. Other European multi-center studies – *Cancer of the Larynx/Hypopharynx: IARC International Case-Control Study*, *IARC Multicentric Cervical Cancer Study*, *IARC International Multicentre Case-Control Study of Cancer of the Oral Cavity and Oropharynx and HPV*, Skin cancer risk factors and safeguarding role of melanins (Helios I and II)- have also been participated in by several Spanish cancer registries. The data from the registries is also used in preparing and monitoring the health plans and in the evaluation of the early detection programs within the scope of their respective Autonomous Communities.

(1) Parkin DM, Whelan SL, Ferlay J, Teppo L, Thomas DB (eds.), *Cancer Incidence in Five Continents*, vol. VIII. IARC, Sci Publ. Lyon: IARC, 2002.

NON-TRANSMISSIBLE DISEASE-RELATED RISK FACTOR SURVEILLANCE SYSTEM AUTONOMOUS COMMUNITY OF MADRID

The Autonomous Community of Madrid put the Non-Transmissible Disease-Related Risk Factor Surveillance System into operation in 1995 for the purpose of ascertaining the distribution and evolutions of the risk factors in relation to behavior and preventive practices. This information serves for preparing public health intervention policies and evaluating their impact on the population. The target population of this study is, on one hand, the adult population within the 18-64 age range and, on the other, the youths within the 15-16 age range.

In methodological terms, the information on adults is based on a system of continuing telephone surveys conducted as per the Behavioral Risk Factor Surveillance System model set out in 1984 in the United States by the CDC's (Centers for Disease Control and Prevention). The survey on the youth population is based on series surveys conducted in April every year by way of a questionnaire filled out at school by each individual child. The adult population information has been made available since 1995, and the youth information since 1996.

The adult questionnaire is comprised of a core of questions which has been kept the same since 1995, and another flexible section which is modified yearly concerning the public health organization. The core questionnaire gathers information on physical activity during regular working time and during free time, the foods eaten within the last 24 hours, dieting, body size based on self-stated height and weight, smoking, drinking alcohol; preventive practices (blood pressure and cholesterol checks, having cytologies and mammograms), accidents and traffic safety. The flexible part has gathered information since the start on primary cancer prevention, perception of health condition, known prevalence of diabetes as well as asthma, perception of environmental risks, women's health and eating behaviors.

The youth questionnaire is quite similar to that of the adults, although it does not include preventive practices, but does however add sections on illegal drugs and sexuality.

Source: Public Health Institute of the Autonomous Community of Madrid

HOSPITAL TUMOR REGISTRY OF THE "HOSPITAL DEL MAR-IMASS"

This Registry has been functioning since 1978 and gathers information on all of the cases of malignant cancer (invasive and in-situ) and on the borderline tumors with the exception of basal cell carcinomas of the skin of those patients for which care has been provided at the "Hospital del Mar" in Barcelona.

In addition to the data on the characteristics of the patients and the tumors (including TNM), including data on treatments, channel through which admitted to hospital, dates of the different events, clinical management, tumor committees, cancer care quality indicators, etc.

This registry has had a computerized pathological anatomy and hospital release-based case detection system since 1992, by means of a data processing system integrated into the hospital computer system. It also has a computerized follow-up system.

This system adds 110-1200 new cases yearly, and the database includes a total of over 19,000 records.

SWDISH CANCER ENVIORNMENT REGISTRY

A major interest has existed for many years in studying and ascertaining the role which environmental factors play in the etiology of cancer. The Swedish Cancer Environment Registry (CER) is based on linking the cancer case notifications of the Swedish national Cancer Registry to the demographic and occupational information obtained from the 1960 and 1970 population censuses.

This registry makes it possible to monitor the incidence of cancer of 4.2 million individuals who contribute for a total of 69 million individuals/year. They have additionally developed different exposure-occupation matrixes and, given the efficiency of the entire system, is it being implemented as a resource used by researchers worldwide and imitated by other countries.

SMALL AREA HEALTH STATISTICS UNIT (SAHSU)

The Small Area Health Statistics Unit (SAHSU) was established in 1987, following a recommendation of the Black Report on incidence of leukemias in young children and adolescents within the nearby vicinity of the Sellafield nuclear power plant. The main objective of the SAHSU has been to evaluate the health risk of the populations due to environmental exposure, emphasizing the use and interpretation of health statistics (mortality and morbidity).

Based on the development and maintenance of a morbid-mortality database, spatially referenced employing postal codes, the SAHSU is able to evaluate occupational, environmental exposures, controlling the social type of skewing factors at the small-area level. This allows them to provide fast response to ad hoc questions posed by different instance concerning unusual disease clusters, particularly in the nearby vicinity of industrial facilities. This department has become a reference point in small area-related statistics analysis methodology and for the dissemination of information on methodological developments.

www.sahsu.org

3.8 RESEARCH

3.8.1 Background information

Analysis of the current situation of cancer research within the national and international context

An analysis of the current structure of the cancer research system in Spain reveals a **current situation** characterized by the following statements:

- **Low level of funding** of cancer research, which has a bearing on the limited production of useful scientific findings (an initial measure of this usefulness is that these findings give rise to publications which are truly competitive at the international level).

The investment in research and development in our country has stagnated over the past few years (0.97% of the GNP in 2002) and is still quite far from the average investment of the European countries. This gap may be widened if the economic resources necessary for nearly 3% of the GNP in research proposed for the year 2010 by the Office of the Spanish President at the summit meeting in Barcelona are not earmarked for this purpose.

- **Little critical mass in research.** Although there be groups of renowned competence and international prestige in our country, these groups are few in number and are spread rather irregularly throughout the country (being concentrated particularly in Madrid and Barcelona) with few actual functional interactions amongst them. These groups are clearly insufficient in number and fewer than in other countries of a economic and cultural level similar to those of Spain. Lastly, clinical research is neither recognized nor vales at the hospitals. The parameters by which a hospitals and their management teams are evaluated never include clinical, basic, epidemiological or other types of research or teaching-related aspects, although they be termed “university hospitals”.
- ✓ There is also a *dispersion of the working groups*, with very few actual interactions amongst them. This weakness is even more accentuated within the hospital scope, with very little basic research and often no connection at all among basic, clinical and epidemiological research. Hence the great importance of the incorporation of quality basic and

clinical research personnel, the creation of spaces devoted specifically to research laboratories at healthcare centers and fostering the collaboration among groups of different university disciplines, public research organizations and hospitals, as well as facilitating access to and use of technologically complex resources. This entails a greater and more rational provision of resources and the boosting of hospital and group networks of excellence which are interconnected with one another.

- ✓ Another weak point is the *lack of technical personnel* well-trained in certain areas who are sufficiently skilled to deal with the continuous technological changes. One main line along which action must be taken is the creation of a minimum critical mass of researchers and research assistants, with the setting up of a professional career not linked to civil service systems.
- ✓ Total lack of a professional career in research no linked to civil service.
- ✓ *Major deficits in relation to know-how transfer-related aspects* between public centers and companies. There is a major deficit in the public research organizations of consulting and of a dynamic, flexible, efficient managerial area. Apart from this, a deficit also exists in Spain with regard to the number of experts on the subject of intellectual and industrial property, the training of whom entails two inseparable aspects of utmost importance – one of which is scientific and the other legal – it thus being necessary to foster the training in this area.
- **Marked division and lack of connection among basic, clinical and epidemiological cancer research in our country.** The lone cases of good basic and/or clinical cancer research conducted at academic or healthcare center in Spain have very seldom established any mutual interrelations, thus losing out on major possibilities of mutual enrichment. The cancer research at the epidemiological level is highly limited, there being a mayor need of creating and sharing new databases, registries, etc., contrasted by criteria of international quality.
- **Cancer research is not perceived as added value, an absolute need or as a priority by Spanish society.** Managing to overcome this gap between science and society is a fundamental challenge, but which is of tremendous

importance for giving substance to the role of research in our country and providing it with the basis of social support it currently lacks.

- **Organization of the Spanish healthcare system structured around the Autonomous Community system.** Within this autonomic context, it is necessary for organizations operating under the authority of the Ministry of Health and Consumer Affairs and the Ministry of Science and Technology, such as the “Instituto de Salud Carlos III” (Ministry of Health) or the Biomedicine Commission of the Ministry of Science and Technology to be identifiable as institutions on a nationwide scale having *the authority and resources to perform a function of integrating cancer research* at the nationwide level.

Need of cooperative research networks

The current status of cancer research in our country shows some major strong points, whilst there however are some areas having major gaps to be bridged. On one hand, worthy of special note is the contribution on the part of Spanish researchers, at the individual group level, to the knowledge of tumor cell molecular biology and to the treatment of this disease. Similarly, there are research centers in Spain of a scientific-technical and human resources-related level which may make them totally competitive at the international level in cancer research. Despite this, many centers have still not been able to reach the point of being able to compete on equal terms with similar organizations in other countries, due mainly to the traditionally endemic problem of a lack of stable funding at the individual center level for both infrastructures and personnel.

Contrasting with the fine quality of the research centers and groups, our country is clearly lagging behind other countries in its environment in many areas of crucial interest for oncology. For example, there is still as yet no stable platform in our country making the existence of a good national system for storing, cataloguing and supplying tumor samples, we still as yet lacking a optimum development of a population-based tumor registry system, and we are far behind other countries in clinical and translational initiatives such as the development of new treatment routes, diagnostic methods and technologies to aid in the diagnosis and treatment of cancer patients.

Up to this point in time, these gaps are being bridged by lone initiatives on the part of individual researchers, groups and/or research centers. However, given the

impact which cancer has on the population, the success of this research can be achieved solely through cooperative, multi-center initiatives. These initiatives could correct four essential shortcomings in our current system: a) the lack of a nationwide effort to assure statistical and epidemiological cancer incidence data in all of the Autonomous Communities in our country b) the lack of access on the part of many of our research groups to cutting-edge technologies (such as, at this point in time, genomic and proteomic technologies) c) the lack of technical and scientific personnel to serve as a catalyst for the advancement of the new areas which are being developed at this time in the realm of oncology and, lastly, d) the lack of recognition, of established structure and of earmarking of material and human resources for clinical research.

The crucial importance these problems have for our country have led to the recent setting up of theme-based cooperative cancer research networks (“Instituto de Salud Carlos III”, 2003). The objective of these networks is to set up stable collaborating mechanisms among the main cancer research centers which will assure the training and scientific and technical personnel, the use of cutting-edge technical resources by all researchers throughout the country in order to develop new technologies and treatment routes and, lastly, to achieve the functioning of national networks which will assure population-based registry and tumor bank systems. In this last instance, the networks are intending to optimize the use of currently dispersed human and technical resources to assure an expeditious transfer of the research done to the hospital and biopharmaceutical fields. On the other hand, these theme-based networks will provide the suitable basis for Spanish groups to participate in functionally similar cooperative networks comprising part of the Sixth European Framework Program. The current text of the 2004-2007 National Biomedicine Plan (Ministry of Science and Technology, 2003) and of the Sectorial Health Research Initiative (Ministry of Health and Consumer Affairs, 2003) includes further strengthening the activities of theme-based networks such as that mentioned herein for cancer.

In short, the NHS Integral Cancer Plan must be based upon and utilize all of the work and the infrastructure generated and achieved through the recently-created theme-based cooperative research of cancer centers and groups promoted by the “Instituto de Salud Carlos III (Tables 3.5 and 3.6; also see <http://www.retics.net>, <http://www.rticcc.org/>) and also make best use of all of the existing resources not integrated into the network of clinical, basic and epidemiological research of renowned standing and proven scientific quality.

TABLE 3.5 CURRENT NODES OF THE THEME-BASED NETWORK FOR COOPERATIVE RESEARCH AMONG CANCER CENTERS

Centro Nacional de Biotecnología, DIO-CNB (Madrid)
Instituto de Investigaciones Biomédicas, IIB (Madrid)
Centro Nacional de Investigaciones Oncológicas, CNIO (Madrid)
Hospital 12 de Octubre (Madrid)
Hospital Clínico San Carlos (Madrid)
Instituto de Investigaciones Biomédicas August Pi i Sunyer, IDIBAPS (Barcelona)
Fundación Parc de Recerca Biomèdica de Barcelona, FPRBB (Barcelona)
Hospital de la Santa Cruz y San Pablo (Barcelona)
Hospital Germans Trías i Pujol, HUGTiP (Badalona)
Hospital Vall d'Hebrón (Barcelona)
Instituto Catalán de Oncología (Hospitales de Llobregat)
Facultad de Medicina (Santiago de Compostela)
Centro de Investigación del Cáncer, CIC (Salamanca)
Instituto Aragonés de Ciencias de la Salud (Zaragoza)
Instituto Universitario de Oncología del Principado de Asturias, IUOPA (Oviedo)
Instituto Canario Investigación del Cáncer, ICIC (Santa Cruz de Tenerife)
Centro Vasco de Investigación del Cáncer, CVIC (Vitoria)
Hospital Virgen de la Nieves, HUVN (Granada)
Hospital Virgen de la Arrixaca (Murcia)
Clínica Universitaria de Navarra, CCUN (Pamplona)
Hospital Marqués de Valdecilla, HUMV (Santander)
Hospital Virgen del Rocío (Seville)
Instituto Valenciano de Oncología, IVO (Valencia)

TABLE 3.6 THEME-BASED NETWORKS FOR COOPERATIVE RESEARCH AMONG GROUPS ON CANCER-RELATED TOPICS

Molecular pathology of solid childhood tumors. Contribution to the diagnosis and to the personalization of the treatment. (RITSI)

Multiple myeloma and other gammopathies. From genesis to treatment.

Molecular study of pancreatic duct carcinoma.

Molecular pathology of solid childhood tumors. Contribution to the diagnosis and to the personalization of the treatment.

EPICUR-RED. A multidisciplinary network for the study of the etiology, clinical aspects and molecular genetics of urinary bladder cancer.

Identification, analysis and validation of clinical, biological and molecular markers of importance for the improvement of brain tumor prognosis.

Network for the study of transplant infection (RESITRA). Infection and transplant. Invading fungus infection in solid organ and hematopoietic stem cell transplants

New immunogenotype studies in the classification and treatment of acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS).

Application of molecular and cellular biology to the diagnosis and treatment of patients with Fanconi anemia.

Spanish Mastocytosis Network (REMA).

Molecular classification of lymphoproliferative processes.

IM3. Molecular medical imaging and multimodality

Cell therapy.

Relationship of the research area with other areas of the Cancer Strategy

Due to its horizontal nature, the research area must carry out direct interactions with each and every one of the other areas of intervention of the Cancer Strategy. Specifically:

The joint consideration and coordination of the different lines of cancer research (basic, clinical, epidemiological, translational or applied) must take the specific form

of the *getting integrated research departments under way* at those hospitals affording the possibility of an actual functional interaction among the researchers and research work at the clinical, basis or care-providing level. The implementation of a *professional research career* in the NHS would significantly help in this regard.

Fostering networked cooperative research must mean stable support of the Theme-based Network for Cooperative Research of Cancer Centers, at the administrative and economic levels, as the vital backbone providing the basis for beginning to solve the structural problems of cancer research in our country. Thus, the horizontal programs of said theme-based network revolving around research training and exchange or around the development of tissue banks and tumor data and registry have a direct impact on these needs of the Cancer Strategy. The primary prevention area would benefit directly from the results of the horizontal programs of the Theme-based Network for Cooperative Research of Cancer Centers, focusing on genomics and proteonomics, biodata, biostatistical and epidemiological cancer analyses. The early detection area benefits directly from research programs on molecular and cellular technology in cancer diagnosis and research. The adult and childhood care areas can benefit directly from the registry programs, non-invasive methods, animal models and treatment strategies. Developing a specific research program aimed at supporting the palliative care area, a terrain which has been developed only to a very small degree at this point in time.

3.8.2 Standards

- Consider biomedical research as being a necessary activity for the success of any strategy proposing to improve the health of those citizens affected by cancer.
- Foster the integration of research into clinical practice for higher quality of the health services and a better and faster-paced implementation of the scientific advances in cancer prevention, diagnosis and treatment.
- Carry out the research tasks in accordance with ethical and efficiency-related criteria in relation to the public and the patients. Assure that the informed consent is obtained in all cases.

- Guarantee the appropriate levels of quality by means of the implementation of periodical external follow-up and evaluation programs for all of the research activities.
- Prevent discrimination due to age among those groups of patients undergoing research. Promote cancer studies in specific population groups, including children and elderly persons.

3.8.3 Objectives

In terms of the prior analysis of the current situation, the following objectives are identified in relation to cancer research in Spain:

- **Obtain an adequate, stable level of funding** on a medium/long-term basis which will make it possible – and compel – the research groups to compete realistically at the international level.
- **Obtain a minimum critical mass of researchers and research technicians** with the setting up of a professional career not linked to civil service systems. This essential need refers both to scientists per se and to research assistants/technicians.
- **Foster the creation and consolidation of sound, stable research groups** of a certain minimum size which are not dispersed. Promote the assigning of specific spaces for carrying out research work at hospitals.
- **Create a context within which basic, clinical and epidemiological research will be interconnected and not separate from one another.** This entails further strengthening the *networks of centers and/or groups of excellence* in cancer research which are truly functionally interconnected with one another.
- **Promote an objective, common evaluating system** for research in general and for cancer in particular at the nationwide level. Periodical revisions of the research centers and of the groups comprising these centers which must assure equal terms for gauging the productivity and competitiveness of any group researching cancer anywhere in the country. This mechanism shall afford the possibility of and assure that the finest science will be funded.

- **Make a communicating effort on the part of the health authorities and the scientific community concerning the crucial need for cancer research.** A determined determination on the part of the institutions and the researches and a continuing citizen information and education endeavor conveying the importance of cancer research as a key element in the future development and well-being of our country.
- **Maintenance and updating of researcher databases at the national level.** The data on applicant center recently accepted into the Theme-based Network for Cooperative Research of Cancer Centers, along with the databases of different research associations (cooperative groups, the Spanish Cancer Research Association, the Spanish Society of Oncological Medicine, etc.) may be the starting point of a national database listing all of the cancer research groups and centers in the National Health System.

These objectives fully tally with the subprograms set out for the different diseases, considered within the biomedicine area of the 2004-2007 National R+D Plan (Ministry of Science and Technology, 2003) or of the Sectorial Health Research Initiative promoted by the Ministry of Health and Consumer Affairs (2003).

3.8.4 Critical points

- The consideration and unified, joint coordination of all of the different lines of research (basic, clinical, epidemiological, translational or applied), independently of their nature thereof or where they are conducted or managed. This entails getting *integrated clinical-basic-translational research departments* under way within the hospital environment, the *development of the professional research career* and others.
- The further strengthening of **online cooperative research** which will provide the basis for beginning to solve the structural problems of cancer research in our country. This involves the implementation of a scientific infrastructure in the State which will support, on a long-term basis, the functioning, funding and evaluation of the cancer research activity at the nationwide level. This point fully tallies with the objectives set out in the *Sectorial Health Research Initiative* (Ministry of Health and Consumer Affairs, 2003), *which, in order to facilitate research of excellence, promotes the creation and accreditation of centers, networks and institutes as well as the fostering of institutional alliances.*

3.8.5 Actions

Basic cancer research plan structure

The current cancer research priorities in our country may be organized around the following lines of research (vertical) and research programs (cross-sectional) (Theme-based network for cooperative research of cancer centers, 2003):

Vertical lines

- Structural analysis at organic and cyto-tissue level of neoplastic disease (imaging and pathological anatomy specialties in their different technologies: endoscopy, echography, conventional and digital radiology, CAT, MNR, PET, gammagraphy, morphostructural phenotyping, etc.).
- Analysis of molecular and cellular mechanisms in the development and progressing of cancer (molecular and cellular biology, structural biology, immunology, genetics and epigenetics).
- Molecular epidemiology, epidemiological research and prevention of sporadic and familial cancer.
- New diagnostic strategies.
- Prognostic factors. Follow-up and evaluation of response to treatment in oncology.
- New treatment strategies.

Transversal programs

For appropriately developing these major lines of research, it is necessary to avail of scientific and technological infrastructure and the proper human resources.

These infrastructures and resources are not available at this point in time at the local level for most of the cancer research groups in our country. It is therefore proposed

to now promote a *structure shared at the national level* which will make it possible to begin remedying these shortcomings and provide a basis for future scientific development. Such a structure may be organized around the following programs:

- Researcher training and mobility and research support program.

This program would be devoted mainly to the enhancement of the human resources necessary for quality cancer research. Actions concerning the following are particularly considered:

- ✓ Third cycle and continued training.
 - ✓ Research personnel training (pre-doctoral, post-doctoral, MD/PhD program, clinical research).
 - ✓ Training of basic and clinical research support personnel.
 - ✓ Researcher exchange and mobility.
- Tumor bank program

It is considered necessary to create and maintain collections of samples of normal and diseased tissues and of cell lines collected under optimum conditions which will afford the possibility of prospective studies and the application of all of the new analysis technologies; the consolidation of the existing tumor banks, stabilizing the necessary human resources and the basic maintenance and management infrastructures; the development of methodologies for the quality control of the material stored, and the promotion of activities, methodologies and resources which will make the coordination among banks possible and will facilitate disseminating and accessing of information and samples by the research groups (LiVolsi *et al.*, 1993; Naber, 1996; Knonen *et al.*, 1998).

- Population-based tumor registries program

Quantification of parameters related to cancer incidence, mortality, survival and prevalence, as well as the time-related trends of these parameters (Jensen *et al.*, 1991, Parkin *et al.*, 1994). To assure the coverage of all of the age groups, the Solid Childhood Tumor Research Network (RITSI) registries must also be taken into account.

- Primary and secondary prevention programs

Utilization of this data in health planning and management within the care-providing, preventive, high-risk group identification and the generation and testing out of etiological hypotheses (López Abente *et al.*, 1996; Hoover, 2000; Moreno *et al.*, 2001; Cancer Epidemiology Service, Instituto de Salud Carlos III, 2003).

- Cancer-related proteomics and genomics program

Development and analysis of mass genomic and proteomic scans to characterize tumor processes and identify patterns of use in diagnosis, prognosis and treatment (Golub *et al.*, 1999; Hanahan and Weinberg, 2000; Harbin, 2000; Scherf *et al.*, 2000; Martin and Nelson, 2001).

- Biodata processing and analysis, biostatistics and epidemiological program (Perera and Westein, 2000; Pito, 2001).

Development and implementation of methodologies for analysis of genomic/proteomic data and statistics, data distribution and inter-center communication, programs for the homogenization of standards useable in statistical and data processing methods.

Analysis of cancer-causing factors and their prevalence among Spain's population; knowledge of the etiopathogenic mechanisms and of the interactions of environmental and genetic factors; development and identification of exposure biomarkers and of tumor susceptibility markers.

- Program for the application of molecular and cellular technology in cancer diagnosis, treatment, follow-up and research (quantitative PCR-type programs, sequencing units, etc.) (Sidransky, 1997; Negm *et al.*, 2002).

Development and standardization of the methodologies and protocols useable in molecular epidemiology, molecular pathology, familial and sporadic cancer prevention and diagnosis, genotype characterization of susceptibility to different types of tumors and genetic counseling programs.

Analysis of large series of patients for initial diagnosis of mutations, confirmation of clinical remission (minimal residual disease detection) and diagnosis of mutations in relapses.

- Non-invasive cancer diagnosis, treatment and research methods program

Favoring new technologies and magnetic resonance (MR) and positron emission tomography (PET) databases having a bearing on the diagnosis, prognosis and evaluation of the treatment response in human cancer and animal models (Stark and Bradley, 1999; Bhujwala *et al.*, 2000; Louis *et al.*, 2000; Seltzer *et al.*, 2002; Kotzerke *et al.*, 2002).

- Animal models in cancer program

Use of murine models currently available for analysis of the genetic and molecular bases of this disease, identification of factors involved in tumor progression, identification of new potential treatment targets and preclinical tests. Development of new alternative models more suitably emulating human disease and allowing for a better control of *in vivo* gene activation or inactivation (Clarke, 2000; Adams and Cory, 1991; Berns, 2001; Van Dyke and Jacks, 2002).

- Program for the development and evaluation of new drugs and other treatment strategies (Lee *et al.*, 2000; Simon, 2001; FESEO, 2002; Clancy and Lawrence, 2002).

- ✓ *Development and evaluation of new antitumoral pharmacological agents*, particularly emphasizing the selection of active agents in initial stages of tumor development, the incorporation of supporting technologies (i.e. pharmacogenomics, proteomics) for optimum preclinical and clinical development of the selected agents, and the individualization of pharmacological treatment according to prognosis-related factors.
- ✓ *Development and evaluation of new pharmacological strategies*, particularly stressing the prevention of tumor development and therapeutic vaccines.
- ✓ *Development and evaluation of non-pharmacological strategies*, such as external radiation therapy and brachytherapy, gene therapy, hematopoietic stem cell transplantation (HSCT), cell therapy and surgery.
- ✓ *Prospective clinical evaluation of the treatment alternatives*, including phase I-IV clinical studies, cost-effectiveness analyses, prognostic models in oncology and the creation of databases covering the population (which also include the elderly on equal terms with other age groups) for evaluation treatment outcomes.

- ✓ Investigation of strategies for the access of the pediatric population to antitumor medications.
- Clinical research program promoted by cooperative groups and group networks. IN collaboration with the scientific societies (Spanish Society of Medical Oncology (SEOM), Spanish Radiation therapy and Oncology Association (AERO), Oncological Pediatrics, Oncology Surgery, etc.) which may serve as advisers to the Ministry of Health and Consumer Affairs and evaluate the proposed researching activity. This entails the development of orphan drugs or of research projects which may be of benefit to patients or citizens which currently lack the support of the pharmaceutical industry.
- Program for the social dissemination of the advances in cancer research.

3.8.6 Examples of good practices

U.S. NATIONAL CANCER INSTITUTE

The National Cancer Institute divides its annual budget (totaling over 4,700,000,000 dollars in 2004) between an Intramural Program located in Bethesda and a nationwide Extramural Program. The funding of the activities of both of these programs is subject to competitive procedures and paired evaluation (Intramural Program: periodical Site Visits. Extramural Program: system of grants evaluated from specific Study Sections). The Intramural Program budget can never exceed 15% of the total NCI budget (usually ranging from 11% to 13%). At least 85% of the total NCI budget is allocated to the Extramural Program, being the main source of competitive funding of cancer research projects and research centers in the country.

The NCI Cancer Centers Program currently maintains 61 research institutions located throughout the country which carry out extensive, coordinated, interdisciplinary, pair-evaluated cancer research programs. These institutions are characterized by their scientific excellence and their ability to integrate a wide range of different experimental approaches to the problem of cancer. Based on its being research-oriented, this program currently covers 8 Cancer Centers, 15 Clinical Cancer Centers and 38 Comprehensive Cancer Centers.

Sources: Intramural and Extramural Research Programs:

<http://cancer.gov/researchprograms>

NCI Cancer Center Network: *<http://www3.cancer.gov/cancercenters>*

SPANISH COOPERATIVE GROUPS IN ONCOLOGY

The cooperative groups have the main objective of promoting and sponsoring quality multi-center clinical research in keeping with the international standards of good clinical practice and the high-level continued training of their members. These groups make it possible to recruit a large number of patients within a reasonable timeframe. They bring together healthcare professionals from different centers which help to answer some of the many questions posed in dealing with the treatment of a certain type of cancer. The multi-center prospective clinical trial is the working tool most used. They furnish new knowledge and contribute to the development of the specialties involved, heightening the level of care provided by the oncology services on coincidentally transferring that which is learned and the clinical trial methodology into daily clinical care.

Different specialists (medical oncologists, radiation therapy oncologists, oncological surgeons, anatomopathologists, radiologists, pharmacists, clinical pharmacologists, epidemiologists, statisticians, molecular biologists, data managers, etc.) are involved in these studies, enriching the outcome of the trial through their different perspectives. Customarily, in addition to the study of the effectiveness and toxicity of the drugs employed, biological samples of the tumor and of the patient are collected, data is obtained from epidemiological surveys, etc, the study of which provides useful data for a better knowledge of cancer and a better interpretation of the results.

There are currently more than 15 cooperative groups in Spain, one example of which is the Spanish group for the treatment of digestive tumors (TTD; <http://www.ttdgroup.org>) is a consolidated cooperative group bringing together over 90 public and private hospitals covering the entire country. Due to their renowned high level of quality and prestige, the cooperative groups collaborate with other international cooperative groups (Pan-European Trials in Alimentary Tract Cancer -PETACC, the Southwest Oncology Group -SWOG, the Breast Cancer International Research Group -BCIRG, the European Organization for Research and Treatment of Cancer -EORTC, etc.) and with monographic cancer research centers in training and research activities.

1. BIBLIOGRAPHY (p. 249)

General aspects (p. 249)

Primary prevention (p. 249)

Early diagnosis (p. 254)

Adult care (p.257)

Child and adolescent care (p. 260)

Quality of life (p. 261)

Palliative care (p. 265)

Information systems (p. 267)

Research (p. 269)

II. WORKING GROUP MEMBERS (p. 272)

Primary prevention (p. 272)

Early diagnosis (p. 273)

Cancer patient care (p. 273)

Child and adolescent care (p. 274)

Quality of life (p. 274)

Palliative care (p. 275)

Information systems (p. 275)

Research (p. 276)

III. SCIENTIFIC COMMITTEE (p. 276)

IV. EXTERNAL REVIEWERS (p. 277)

V. THE IMPORTANCE OF THE GENDER PERSPECTIVE IN THE CANCER STRATEGY (p. 278)

The determining factors of health and disease are not the same for males and females.

Gender (socially constructed female and male traits), not only sex (biological differences), is involved as a determining factor of inequity in the cancer morbidity and mortality processes by interacting with the biological differences and the social factors to give rise to inequitable situations in health risk patterns, in the use of the healthcare services and in health outcomes.

In order for the highest levels of health to be attained, it is necessary for healthcare policies to recognize that females and males, due not only to their biological differences but also and more importantly to their gender roles, have different needs, hindrances and opportunities, and that these aspects must therefore also be taken into account when planning a health strategy.

Employing the gender focus when carrying out a cancer-related intervention entails analyzing the health situations broken down by genders. In addition thereto, an analysis must be made of the psychosocial dimensions determining the outward displays, attitudes and conducts in relation to the other gender, which have a bearing both on the attitude of the persons who are ill but also on that of the professionals who are providing care for these individuals.