WHITE BOOK ON CANCER PATIENTS' RIGHTS

ONCONET SUDOE

Anne-Marie Duguet · André Dias Pereira (Eds.)

André Dias Pereira · Carla Barbosa
Ana Elisabete Ferreira · Eduardo A. da Silva Figueiredo
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O Centro de Direito Biomédico, fundado em 1988, é uma associação privada sem fins lucrativos, com sede na Faculdade de Direito da Universidade de Coimbra, que se dedica à promoção do direito da saúde entendido num sentido amplo, que abrange designadamente, o direito da medicina e o direito da farmácia e do medicamento. Para satisfazer este propósito, desenvolve acções de formação pós-graduada e profissional; promove reuniões científicas; estimula a investigação e a publicação de textos; organiza uma biblioteca especializada; e colabora com outras instituições portuguesas e estrangeiras.

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I. Introduction

Portugal has a high standard of healthcare services. The Portuguese healthcare system ranked 14th in the 2016 Euro Health Consumer Index (EHCI) — improving its position in 6 places when compared to the previous year and being part of the top 25 since 2012 —, for the first time going beyond the UK and Spain. Portugal performed particularly well for price-quality rankings. Currently, our country spends around 8.9% of its GDP on healthcare, just slightly below OECD averages. Around 70% is public expenditure and 30% private expenditure, with the EU reporting less than 5% coming from social security contributions. The average life expectancy in Portugal is 78 for males and 84.4 for females, above the European average. Portugal has approximately 4.5 doctors per 1,000 inhabitants, which is also slightly above the average in Europe.

In 1976, the Portuguese Constitution was approved and proclaimed the citizens' right to healthcare by "the creation of a universal, free-of-charge National Health System"[5]. In 1979, Basic Health Law re-

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[5] "Article 64 (Health) 1. Everyone has the right to the protection of health and the duty to defend and promote health. 2. The right to the protection of health shall be fulfilled: a) By means of a universal and general national health service which , with particular regard to the economic and social conditions of the citizens who use it, shall tend to be free of charge; b) By creating economic, social, cultural and environmental conditions that particularly guarantee the protection of childhood, youth and old age; by systematically improving living and working conditions , and promoting physical fitness and sport at school and among the people; and also by developing the people's health and hygiene education and healthy living practices. 3. In order to ensure the right to the protection of health, the state is charged, as a priority, with:

gulated the NHS as being a universal and general health system, free at the point of use, *i.e* "a universal, comprehensive and free-of-charge National Health Service".

The overall legal framework of the Portuguese health system is the 90's Basic Law on Health (Law No. 48/90, of 24 August 1990), which introduces various principles for its organization and functioning.

In sum, it is characterized by three co-existing and overlapping systems: the universal NHS; special health insurance schemes for particular professions or sectors (e.g. civil servants, employees at banks and insurance companies), called the health subsystems; and private voluntary health insurance.[6]

In Portugal, the majority of patients are treated in the National Health Service, even when they benefit from alternative health protection systems such as ADSE (public service workers) or SAMS (bank workers) as well as health insurance contracts available from different insurers. These alternative medical insurances can set limits to the medical care provided and when patients reach this limit, treatments continue in the National Health Services.

The healthcare delivery system in Portugal consists of a network of public, social and private healthcare providers.

The National Health Service is the most commonly used system. It was created in 1979, it is universal, and financed by taxes. It is also a national, general, and (tendentially) free system. Healthcare providers are mostly public, both in primary and in hospital care.

The Health Ministry is responsible for allocating funds to the SNS. The overall budget for the SNS is distributed by the various institutions based on historical expenditure. More recently, payment methods have been introduced to cover overall costs for some pathologies. The care model in the area of oncology is comprised of three highly specialised centres (the Portuguese Oncology Institutes), which cover the entire geographical area of Portugal and are supplemented by the provision of care in general hospitals.

Recently, malignant neoplasms became the first cause of death. "According to the latest available data, the main causes of death in 2014 were malignant neoplasms (152.0 deaths per 100 000 population) and circulatory system diseases (150.8 deaths per 100 000 population) (Table 1.3). However, when analysing standardized death rates (SDRs) by gender, SDRs for men are greater than SDRs for women in all causes, except for Alzheimer disease (INE, 2016c). This is in line with the fact that, on average, women live longer than men. In 2014, circulatory system diseases killed 177.9

a) Guaranteeing access by every citizen, regardless of their economic situation, to preventive, curative and rehabilitative medical care; b) Guaranteeing a rational and efficient nationwide coverage in terms of human resources and healthcare units; c) Working towards the socialization of the costs of medical care and medicines; d) Disciplining and inspecting entrepreneurial and private forms of medicine and articulating them with the national health service, in such a way as to ensure adequate standards of efficiency and quality in both public and private healthcare institutions; e) Disciplining and controlling the production, distribution, marketing, sale and use of chemical, biological and pharmaceutical products and other means of treatment and diagnosis; f) Establishing policies for the prevention and treatment of drug abuse. 4. Management of the national health service shall be decentralized and participatory."

[6] See Simões, Jorge de Almeida / Augusto, Gonçalo Figueiredo / Fronteira, Inês / Hernández-Quevedo, Cristina, "Portugal: Health system review", in *Health Systems in Transition*, 19(2), 2017, 1–184. Available online: <http://www.euro.who.int/__data/assets/pdf_file/0007/337471/HiT-Portugal.pdf>.

men per 100 000 population and 128.1 women per 100 000 population, while malignant neoplasms killed 212.9 men per 100 000 and 105.4 women per 100 000. Respiratory diseases were, for both sexes, the third most important cause of death but they accounted for a much lower proportion of deaths: 11.6% of all deaths; SDR: 72.4 men per 100 000 population and 40.9 women per 100 000 population (INE, 2016c). The SDR for circulatory diseases has decreased since 2000 for both men (–41.5%) and women (–44.4%); the SDR for malignant neoplasms has reduced by only 3.3% for men and 9.0% for women over the same period. Between 2000 and 2014, the SDR for colon cancer increased substantially by 51.3% among men and 30.4% among women. Also, among women, the SDR for trachea, bronchus and lung cancers increased from 7.6 to 9.4 (+23.7%) in the same period. Finally, among men, the SDR for suicide more than doubled (+102.7%) between 2000 (7.4 per 100 000 population) and 2014 (15.0 per 100 000 population) (INE, 2016c)."[7]

II. A Statute for Cancer Patients

In Portugal there is no specific legal regulation to determine the rights of cancer patients. Therefore, the general patients' rights legislation is applicable (e.g. Law No. 15/2014, of March 21, on rights and duties of the health service user).

In specific situations, for example in labour law, a comparison between the cancer patient and the person with impairment or disability is accepted. Thus, our legislation positively discriminates the disabled person and also the cancer patient. In fact, according to the World Health Organization (WHO), a disabled person is someone who, due to the loss or congenital or acquired anomaly of a psychological, intellectual, physiological or anatomical structure or function capable of causing capacity constraints, may be considered to be at a disadvantage when engaging in activities considered normal taking into account age, gender and dominant sociocultural factors.

According to Article 2 of Law No. 38/2004, of 18 August, a person with a disability is "one who, due to a congenital or acquired loss of or anomaly in functions or structures of the body, including psychological struggles, presents specific difficulties that may, in combination with environmental factors, limit or impede activity and participation on an equal basis with others".

In turn, the Convention on the Rights of Persons with Disabilities provides that the States shall ensure the personal mobility of persons with disabilities, with the highest possible level of independence, by facilitating access to mobility aids through assistive devices and technologies; considering that the above mentioned Law No. 38/2004, of 18 August, which defines the general bases of the legal regime for the prevention, empowerment, rehabilitation and participation of persons with disabilities, provides that it is the responsibility of the State to provide, adapt, maintain or renew the appropriate means of compensation, with a view to greater autonomy and adequate integration of these persons.

The assessment of the degree of incapacity, which will result in their access to certain rights/benefits is therefore, as we will see, reflected in the Medical Certificate of Multipurpose Incapacity ("*Atestado Médico de Incapacidade Multiuso*"). This

[7] Simões, Jorge de Almeida / Augusto, Gonçalo Figueiredo / Fronteira, Inês / Hernández-Quevedo, Cristina, "Portugal: Health system review", *op. cit.*, p. 8.

document attests that the cancer patient has a certain percentage of disability, and to obtain part of the rights/benefits that we shall mention, a percentage of incapacity equal to or greater than 60% shall be decreed, such as: exemption of automobile tax, benefits in the individual revenue tax, exemption of hospital moderation fees, etc.

III. NATIONAL PROGRAMME FOR ONCOLOGICAL DISEASES

The National Programme for Oncological Diseases or, as it was previously known, the National Plan for the Prevention and Control of Oncological Diseases, is an extremely important resource that made it possible to analyse the health status of oncological diseases in Portugal and draw up objectives and strategies to be pursued in the years following the programme/plan's implementation.

The 'National Plan for the Prevention and Control of Oncological Diseases 2007-2010" (PNPCDO) defined five areas with priority intervention: prevention, cancer registries, screening, integrated treatment and training.

In 2012, the National Programme for Oncological Diseases was considered a priority and along with seven other programmes came under the remit of the Directorate-General for Health.[8]

Six years since the publication of these programme guidelines, the truth is that some of its goals and strategies have been achieved. The National Programme for Oncological Diseases (PNDO) currently in force (published in September 2016) con-

[8] National Programme for Oncological Diseases — Programme Guidelines — available at: <www.dgs.pt>. In 2012, the main objectives of the Programme were:

"(a) to maintain the validity of previous cancer plan recommendations and the recommendation of the Council of Europe (2003/878/EC) to perform screening for cervical cancer by cervicovaginal cytology in women aged between 30 and 60 years of age, breast cancer screening with mammograms every two years in women between the ages of 50 and 69, and screening for colorectal cancer with screening for faecal occult blood for the entire population aged 50-74 years;

b) to increase the total coverage rate of oncological screenings (breast, cervix), guaranteeing more than 60% coverage throughout the country by 2016.

c) develop realistic schedules for widespread screening, in collaboration with the Regional Health Administrations, in line with the resources available on the ground;

d) to combat the centralising dichotomy of care versus community-based care, which rather than antagonistic should be seen as cooperative. To sponsor the formal affiliation of peripheral units to central units and initiate pilot projects in this area. Not to restrict the network to moving patients, but to encourage the spread of knowledge and the cooperative use of available resources, including sophisticated diagnostic resources;

e) to decide that the information backbone in Oncology should be available for cancer registries; as Portugal is in the enviable position of having regional, population-based cancer registries, this would provide full coverage of the country (with an approved national registry since 2017);

f) the existence of several data entry platforms and the lack of automation in data capture methods has led to significant difficulties in their operation. Although it is not possible, because of their nature, to provide real-time information, the gap between events and data availability should be shortened to increase the potential of these platforms;

g) a policy of affiliating centres must be initiated to allow the exchange of experiences and to make the available resources more profitable;

h) the national tumour bank network is currently being finalised. The computer system common to all banks should be implemented to increase their scientific potential;

i) clinical research in oncology should be an integral part of National Health Service activity, and inter-hospital affiliation and autonomous development programmes should be prioritised;

j) basic research in oncology must also be integral, with translational research being particularly important, and research which uses synergies between academic and hospital institutions".

Along with these objectives the following strategies were outlined:

"a) centralise the Oncology Programme Department for monitoring screening programmes. The establishment of a committee to monitor screening with the participation of staff nominated by their respective ARS directorates. The

tains the health status assessment for 2016 and the programme guidelines for the years 2017 to 2020.

As regards the state of health in 2016, the PNDO concludes that over the last few years we have seen a regular increase in the incidence of cancer in our country, as in the rest of Europe, at a steady rate of approximately 3% per year.

"This increase is a result of the ageing population, caused by the growing success rate in treating both cancer and other pathologies, increasing the likelihood of new neoplasms. These factors are combined with changes in lifestyles, which have had a significant impact on the incidence of cancer.

In addition to changes in the number of new cases, there has also been a change in the average age of patients, the pattern of neoplasia and the needs of our patients, which have become increasingly complex.

The avoidable causes of cancer are highly significant, and the role of tobacco as the most important avoidable cause can never be overemphasized. Other known risk factors, such as exposure to sun, poor diet, obesity, excessive alcohol consumption and some viral infections are important areas for educating citizens in health literacy".

In 2016, there was a significant expansion in cancer screening programmes, with more users being screened and a higher take-up rate. Interventions aimed at reducing the incidence of cancer in Portugal are the future. Taking primary prevention measures to promote healthy behaviours (changes in lifestyles and vaccination programmes) and secondary prevention (early diagnosis) are the only way to mitigate the current cancer epidemic.

By 2020, which is the year when the new programme comes into force, the Directorate-General for Health will present the following objectives to be met under the current programme: to make cancer screening programmes accessible to all Portuguese citizens; reduce mortality associated with preventable tumours; 100% national coverage for breast, cervix and colorectal cancers (which have the highest incidence in Portugal); promote integration between primary health care and hospital care for three oncological diseases; reduce the number of operations performed after their scheduled completion date to less than 10%.

The goals to be achieved in 2020 are: to promote the integration of care between primary health care and hospital care for three oncological pathologies; reduce the percentage of oncological

generalisation of successful experiences, sharing knowledge among the different regions;

b) draft a national standard for breast, cervix and colorectal cancer screening in accordance with European directives to be completed by the end of 2012;

c) discourage opportunistic screening and carry out population-based screening instead;

d) start linking screening programmes to regional cancer registries, as provided for in the European Directive, so that a complete quality control programme can be established;

e) carry out an up-to-date survey of oncology units in Portugal: who does what, how, where and under what conditions. This survey has to be ready by the end of 2012;

f) together with the National Oncology Council, identify pathology groups and diagnostic and therapeutic procedures that require centralisation, and the minimum resources necessary to carry out selected initiatives, establish minimal cases in pathologies/procedures, so as to ensure quality and rationality in care provision;

g) reactivate the Regional Oncology Committees, based in the Regional Health Administrations, according to the regulation already approved in Ordinance No. 1355 of 2002 ("Portaria n.º 1355 de 2002"), and make them the instruments for monitoring and implementing the network;

h) standardise the information available on the various platforms,

i) improve the participation of hospitals in entering data into registries;

j) monitor the data contained in them, both in terms of completeness and accuracy, with programmed audits;

l) associate hospital funding with collaboration on registries, which is the only way of making it a priority for providers;

m) launch the foundations of an oncology research network.

surgeries that surpass the Maximum Guaranteed Response Time (MGRT) to fewer than 10% by 2020 and expand the coverage of population-based oncological screenings nationwide and increase geographical coverage rates by 2020: breast cancer screening: 100%, cervical cancer screening: 100%, colon and rectal cancer screening: 100%".

IV. Patients' General Rights

While in subsequent chapters we shall examine several specific patient rights, we must also mention those which are generally granted to all patients.

On March 21, 2014 a law was published that consolidated the legislation on the rights and duties of the health service user — Law No. 15/2014, of 21 March. This law consolidated the principles of several laws: Law No. 14/85, of 6 July — accompanying pregnant women during labour; Law No. 33/2009, of 14 July — right to be accompanied for users of National Health Service (SNS) emergency services; Law No. 106/2009, of 14 September — family accompaniment on hospital admission; Law No. 41/2007, of 24 August — Healthcare Access Charter of Rights for National Health Service (SNS) users. This created a single text containing the principles underlying health service users' duties and rights.

Among the rights of patients, the following should be highlighted:

- the right of choice (the health service user has the right to choose healthcare services and providers, according to existing resources);
- the right to informed consent (consent or refusal to provide health care must be declared freely and clearly, unless otherwise provided by law, after adequate information has been delivered to the patient);
- the right to adequate healthcare provision (the health service user is entitled to receive the health care that he/she needs, promptly or within a time period considered clinically acceptable, depending on the particular circumstances; health care must be provided humanely and with respect for the patient);
- the right to confidentiality and personal data protection;
- the right to information;
- the right to be accompanied and to receive visits. Law No. 15/2014, of 21 March — Patient's Rights and Duties Act — regulates the *Right to companionship* that is important for humane treatment in hospital settings. Art. 12 recognises the right to family support "for people with incurable disease at an advanced stage and the final stage of life." Ascendants, descendants, the spouse or partner or any other person designated by the patient have the right to stay in the hospital with the patient.[9]

The right to informed consent is of upmost importance for cancer patients. Back in the 90´s, there was already a consensus in Europe concerning the need to respect and to promote the autonomy of the patient, based on the dignity of every human being. Therefore, on the 4th of April 1997, in Oviedo (Asturias, Spain), the member States of the Council of Europe (some other States and the European Community) agreed to approve the Con-

[9] Pereira, André Dias, "Le Portugal: a pays agé avec une législation moderne", in *Les proches et la fin de vie medicalisée* (Dir. Brigitte Feuillet-Liger), Bruxelles: Bruylant, 2012.

vention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine.

The Convention is really a "patients' rights treaty"[10] and one of the basic principles of this Convention is the respect for informed consent. Thus, Chapter II concerns Consent[11] and Art. 5 states:

> *"An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.*
>
> *This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.*
>
> *The person concerned may freely withdraw consent at any time."*

The right to informed consent is also proclaimed in Charter of Fundamental Rights of the European Union[12], more specifically in Art. 3 (2):

> *"1. Everyone has the right to respect for his or her physical and mental integrity.*
>
> *2. In the fields of medicine and biology, the following must be respected, in particular (…) the free and informed consent of the person concerned, according to the procedures lay down by law".*

We shall also consider the Declaration on the promotion of patients' rights in Europe,[13] which states in Art. 2.2.: "Patients have the right to be fully informed about their health status, including the medical facts about their condition; about the proposed medical procedures, together with the potential risks and benefits of each procedure; about alternatives to the proposed procedures, including the effect of non-treatment; and about the diagnosis, prognosis and progress of treatment."

Concerning national law of European States, one must also consider the proposal of the Study Group on a European Civil Code concerning the Treatment Contract, which is an important comparative law study and considers the contributions of different legal systems:[14]

Article 7: 105: Duty to Inform of the Treatment Provider

(1) The treatment provider must, in order to give the patient a free choice regarding treatment, and in a way understandable to the patient, in particular inform the patient about:

a. The patient's health status;

b. The nature of the proposed treatment;

c. The advantages of the proposed treatment;

d. The risks of the proposed treatment;

e. The alternatives to the proposed treatment as well as their advantages and risks as compared to those of the proposed treatment;

f. The consequences of abstaining from any treatment.

(2) The treatment provider must, in any case, inform the patient about any risk or alternative that may reasonably influence a patients decision on whether to give consent on the proposed treatment or not.

[10] Nys, Herman, "La Convención Europea de Bioética. Objetivos, principios rectores y posibles limitationes", in *Revista de Derecho y Genoma Humano*, n.º 12, 2000, pp. 78-80.

[11] Issues of competence of "capacity to consent", problems of the right to consent and withdrawal of consent and the right to refuse treatments will not be dealt here.

[12] The Treaty of Lisbon preserves existing rights while introducing new ones. In particular, it guarantees the freedoms and principles set out in the Charter of Fundamental Rights and gives its provisions a binding legal force; it concerns civil, political, economic and social rights.

[13] Amsterdam, March 1994, WHO, Regional Office for Europe. The right to information and the right to consent are well distinguished.

[14] Barendrecht, Maurits / Jansen, Chris / Loos, Marco / Pinna, Andrea / Cascão, Rui / van Gulijk, Stephanie, *Principles of European Law, Study Group on a European Civil Code, Service Contracts*, Sellier, 2007, p. 781 ff.

A risk is presumed to be capable of influencing that decision of its materialisation leads to serious detriment to a patient in that situation. (…)

Article 7: 106: Duty to inform in case of Unnecessary or Experimental Treatment

If the treatment is unnecessary in respect of the patient's health condition, all known risks must be disclosed.

If the treatment is experimental, all information regarding the objectives of the experiment, the nature of the treatment, its advantages and risks and its alternatives, be it only potential, must be disclosed."

Article 7: 107: Exceptions to the Duty to Inform

(1) The information that must be provided under Article 7:105 and 7:106 may be withheld from the patient:

a. If there are objective reasons to believe that it would seriously and negatively influence the patient's health or life; or

b. If the patient expressly states that the patient wishes not to be informed, provided that the non-disclosure of the information does not endanger the health or safety of third parties.

(2) Article 7: 105 does not apply if treatment must be provided in an emergency. In such a case the treatment provider must, as far as possible, provide the information later

In all European countries the patient has a right to be informed, to make an informed choice in regard to treatment and to consent in regard to his physical integrity and right to self-determination.

As in most civil law countries, the burden of proof of disclosure of information lies with the physician.

Some arguments in favour of this doctrine are the following: (1) the impossibility of proving a *negative fact* (not being informed); (2) Informed consent is a justification for an attempt to physical integrity, thus the party that uses the defence (or justification) must prove all its requisites; (3) this allows a certain equality of weapons in the process and equality in the application of the law[15].

V. National Health Service

The rights referred to below are not exclusive to cancer patients, nor is it an exhaustive list. However, mindful of the difficulties experienced by these patients, these rights are those whose exercise is paramount.

We refer to the situations in which the legislation includes rights featuring:

- the exemption of fee rates in the National Health Service (for patients who have a medical certificate of multi-use disability with a degree of incapacity equal to or greater than 60%),
- legal assistance for the reimbursement of medicines and prosthetics and other support materials,
- and the exercise of the right to access their health information, for example to obtain a second medical opinion.

i. National health service charges

Under Article 64 of the Constitution of the Portuguese Republic everyone has the right to health protection and the duty to defend and promote it.

The right to health protection is achieved: through a universal and general national health service which, taking into account the economic and social circumstances of citizens, is generally free of charge.

[15] Pereira, André Dias, *O Consentimento Informado na Relação Médico-Paciente*, Coimbra: Coimbra Editora, 2004, p. 190-200.

The right to health protection is also achieved by creating the economic, social, cultural and environmental preconditions which guarantee the protection of children, young people and senior citizens, and the systematic improvement of living and working conditions, as well as the promotion of a physical, sporting, school and popular culture, and by the developing people's health education and healthy living practices.

In order to ensure the right to health protection, it is primarily the responsibility of the State to:

a) Guarantee access of all citizens, regardless of their economic circumstances, to preventive, curative and rehabilitative medical care;

b) Ensure rational and efficient coverage of the entire country in human resources and health units;

c) Direct its action towards the socialization of the costs of medicines and medical care; etc.

The Portuguese National Health Service is therefore a free system for which users only have to pay user charges (a very low amount given the cost of the services they use). However, there are situations in which exemption from user charges is granted. One such condition is cancer patients with a degree of disability equal to or greater than 60%.

System of user charges: Decree-Law No. 113/2011, of 29 November, as amended by Decree-Law No. 128/2012, of 21 June, by Decree-Law No. 133/2012, of 27 June, by Law No. 66-B/2012, of 31 December (Lei n.º 66-B/2012, de 31 December), by Law No. 51/2013, of 24 July by Decree-Law No. 117/2014, of 5 August, by Decree-Law No. 61/2015, of 22 April and by Law No. 7-A / 2016, of 30 March.

ii. Reimbursement of medicines

Decree-Law No. 48-A/2010, of 13 May, as amended by Decree-Law No. 106-A/2010, of 1 October, provides for the possible reimbursement of the cost of medicines through a general scheme and a special scheme (Hospital Pharmacy Waiver or Shop Pharmacy Waiver), which applies to specific situations that cover certain pathologies or groups of patients.

The State's contribution to the price of medicines for sale to the public is set according to the following bands:

- Band A — 90%;
- Band B — 69%;
- Band C — 37%;
- Band D — 15%.

Reimbursement levels vary according to the therapeutic indications of the drug, its use, the entities that prescribe it and the increased consumption for patients suffering from certain pathologies: Ordinance No. 924-A/2010, of 17 September, as amended by Ordinance No. 994-A/2010, of 29 September and by Ordinance No. 1056-B/2010, of 14 October if they are not included in the list of medicines considered essential for sustaining life.

There is some specific legislation for cancer patients. Narcotic analgesics, namely opioid drugs, are eligible for Band C (37%) level subsidy under the general outpatient scheme. However, in the case of medicinal products essential for treating moderate to severe oncological pain, it is important, on grounds of public health, to reduce the prevalence of pain, to facilitate patients' access to this therapy, to promote equity and universality of pain treatment, and contribute to a significant improvement in cancer patients' quality of life. There

is therefore considered to be a public interest in assigning Band A (95%) subsidy for opioid medicines when prescribed for the treatment of moderate to severe oncological pain.

It should also be noted that in 2015 the National Health Technology Assessment System (SiNATS) was created. It prescribes that health technology assessment should include other health technologies besides medicine, such as medical devices.

National Health Technology Assessment System (SiNATS): SiNATS was created by Decree-Law No. 97/2015, of 1 June establishing, among other matters, the regulations applicable to the State's contribution to the price of medicines.

Pharmacotherapeutic groups and subgroups of medicines may be subject to reimbursement and to the following reimbursement levels: Ordinance No. 195-D/2015, of 30 June.

Pensioners: Article 19 of Decree-Law No. 48-A/2010, of 13 May, pursuant to the provisions of Article 39(3) of Decree-Law No. 97/2015, of 1 June and Article 4 of Ordinance No. 195-D/2015, of 30 June, as well as Ordinance No. 91/2006, of 27 January), as amended by Decree of Rectification No. 12/2006, of 16 February and by Ordinance No. 314/2006, of 3 April, and Order No. 12188/2006, of 9 June (system applicable to beneficiaries of ADSE [Civil Servants' Health Assistance Programme], by virtue of Ordinance No. 728/2006, of 24 July).

Contribution to the price of opioid medicines for the treatment of moderate to severe cancer pain: Order No. 10279/2008 of 11 March, with amendments, related to the list of medicines included, introduced by Order No. 22186/2008, of 19 August, by Order No. 30995/2008, of 21 November, by Order No. 3285/2009, of 19 January, by Order No. 6229/2009, of 17 February, by Order No. 12221/2009, of 14 May, by Declaration of Rectification No. 1856/2009, of 23 July, by Order No. 5725/2010, of 18 March, by Order No. 12457/2010, of 22 July, by Order No. 5824/2011, of 5 March and by Order No. 57/2014 of 19 December.

iii. Reimbursement of expenses for prosthetics and other support products

The Support Products Allocation System, called SAPA, aims to allocate products to support people with permanent and temporary disabilities by carrying out a comprehensive, integrated and transversal policy to compensate and mitigate their limitations on activity and restrictions on participation.

Considering that the Convention on the Rights of Persons with Disabilities provides that it is the responsibility of State parties to ensure the personal mobility of people with disabilities as widely as possible by facilitating access to mobility aids through support devices and technologies; considering that Law No. 38/2004, of 18 August, defining the general basis of the legal system on the prevention, empowerment, rehabilitation and participation of persons with disabilities, provides that it is the responsibility of the State to provide, adapt, maintain or renew the appropriate financial support, with a view to greater autonomy and adequate integration by those persons; and considering that Decree-Law No. 93/2009, of 16 April created the Support Products Allocation System to which all people with temporary or permanent disabilities can apply, annually, these support products are allocated budgets by governmental order. Subsequently, the order issued by the National Institute for Rehabilitation contains the regulations setting out the funds and consequent allocation of Support Products for Persons with Disabilities.

There is a 100% subsidy when the Support Product (Technical Assistance) is not included in the health subsystem reimbursement tables of which the citizen is a beneficiary, or when it is not reimbursed by an insurance company.

Order No. 10909/2016, of 8 September 2016, from the Ministries of Finance, Education, Employment, Solidarity and Social Security and Health, determines that the 'general procedures of the entities prescribing and financing support products, within the scope of the Support Products Allocation System, are contained in Order No. 7225/2015, published in the Official Gazette ("*Diário da República*"), 2nd series, of 1 July, by the Chair of the Executive Council of the National Institute for Rehabilitation' (point 4).

It adds that 'the general procedures may be amended or revised by order of the Chair of the Executive Council, to be published in the *Diário da República*, 2nd series, after a preliminary hearing by the Directorate-General for Health, Directorate General for Education, Institute for Employment and Vocational Training, Social Security Institute, and the opinion of the Support Products Monitoring Committee (CAPA) (point 5).

Article 8(2) of Order No. 7225/2015 states that 'the request to grant financial support for the purchase of support product(s) must be delivered by his/her own family or legal representative, at the district centre of the area in which the disabled or incapacitated person resides, or at a local social security office, on presentation of a current version of the Support Products Prescription Card issued by a Health Centre or Specialised Prescriber Centre recognized by the Social Security Department (ISS) accompanied by the documentation specified by ISS services, contained in the support product financing procedures manual, available on the ISS web page.

Law No. 38/2004, of 18 August (Lei n.º 38/2004, de 18 de agosto).

Decree-Law No. 93/2009, of 16 April (Decreto-Lei n.º 93/2009, de 16 de abril), as amended by Decree-Law No. 42/2011, of 23 March (Decreto-Lei n.º 42/2011, de 23 de março).

Ordinance No. 192/2014, of 26 September (Portaria n.º 192/2014, de 26 de setembro).

Joint Order No. 3520/2012 (Despacho Conjunto n.º 3520/2012), published in the Official Gazette (*Diário da República*) Series II No. 50, dated 9-03-2012 and Order No. 2671/2014 (Despacho n.º 2671/2014), published in the Official Gazette Series II No. 34, of 30-01-2014.

Order No. 6133/2012 (Despacho n.º 6133/2012), published in the Official Gazette Series II No. 91, of 10-05-2012.

iv. Travel expenses

The cancer patient is entitled to be reimbursed travel expenses for medical care and treatment. The doctor prescribing the treatment is the person who is authorised to sign the travel expenses claim. This document must be delivered to the administrative department at the hospital. Some hospitals have agreements with companies that offer their own transportation.

The National Health Service covers 100% of non-urgent transport costs prescribed for users who are in difficult financial circumstances and where the clinical situation justifies it, in the following terms:

a) Incapacity equal to or greater than 60% irrespective of whether travel is intended for care justified by the incapacity;

b) A disabling clinical condition, as a result of cancer, among other conditions.

For this purpose, persons considered to be in an incapacitating clinical condition include a bedridden patient if he/she need private transport, a person in a wheelchair because he/she are unable

to walk unaided, someone who has difficulty finding their way and/or cannot travel independently on a public road, and so must be transported by ambulance.

The NHS also guarantees 100% of the non-urgent transport costs prescribed to users who are in financial difficulties and in justifiable clinical circumstances, provided that this is carried out in a Single Patient Transport Vehicle ('VTSD').

The transport of patients in financial difficulties and in justifiable clinical circumstances under the aforementioned terms and conditions for the purposes of physiotherapy shall be carried out by the SNS for a maximum period of 120 days, without prejudice to the possibility of extending this period in situations duly justified by the attending doctor, where this has been previously evaluated and authorised on a case-by-case basis by the management body of the SNS entities responsible for paying the charges.

In case of oncological disease, the SNS pays the cost, albeit partially, of the non-urgent transportation of patients, to carry out clinical tests required by their illness, regardless of the number of monthly trips.

Prolonged and continuous healthcare provision should be subject to a single prescription.

Other cases — namely rehabilitation, physiotherapy and other situations duly justified by the attending doctor — may be considered. In this occasion, if the treatment in question is not directly connected to the oncological illness, the decision on transport should be evaluated by the body concerned.

The non-urgent transportation of patients receiving health treatment, as well as any public or private entities responsible for their care,[16] is excluded from these regulations.

Decree-Law No. 113/2011, of 29 November

Ordinance No. 142-B/2012, of 15 May, as amended by Ordinance No. 178-B/2012, of 1 June, by Ordinance No. 184/2014, of 15 September, by Ordinance No. 28-A/2015 of 11 February and by Ordinance No. 83/2016, of 12 April.

Order No. 7702-C/2012, of 4 June, as amended by Order No. 8705/2012, of 29 June.

VI. Others

i. Advance directives

In 2012, Law No. 25/2012, of 16 July, which regulates living wills, was approved in Portugal. Law No. 25/12 limited the subject matter of living wills to health care, *i.e.* it circumscribed the subject matter of living will declarations to decisions that are related to the grantor's health and that are addressed to their doctor.

Article 2(2) provides a list of provisions which may be contained in a living will. For example, under the terms of subparagraph (a), 'the provisions of the living will document expressing the wishes … of the grantor … may include '*not being given artificial life support treatment*'.

One of the new features that this law has brought is the creation of a figure already known in legal doctrine and other legal systems: *the health care proxy*. Any person may now appoint a health care proxy, granting him or her representative powers to decide on the health care to be received

[16] Liga Portuguesa Contra o Cancro, *Direitos Gerais do Doente Oncológico*, 3.ª Edição, 2016, available at: <https://www.ligacontracancro.pt/direitos-gerais-dos-doentes-oncologicos/>.

or not received by the grantor when the latter is unable to express his or her personal and autonomous will. Decisions taken by the health care proxy, within the limits of the representative powers that are incumbent on them, must be respected by the professionals who provide health care to the grantor, under the terms of this law. However, this figure is still not very popular, as there are only an approximate number of 25.000 citizens who registered an advance directive.[17]

System of advanced directives on wills, appointment of healthcare prosecutor and creation of the National Registry of Living Wills: Law No. 25/2012, of 16 July.

Organization and operation of the National Registry of Living Wills: Ordinance No. 96/2014, of 5 May.

Approves the advanced will policy model: Ordinance No. 104/2014, of 15 May.

ii. Preservation of fertility and medically assisted procreation

Oncologic treatment prolongs the average life expectancy of patients, but has deleterious effects on their reproductive function. Also, we notice the increase of incidence of certain tumours at younger ages and the current tendency to postpone the first child. Moreover, it should be noted that young age is generally a factor of bad prognosis and, consequently, often involves the need for radiation therapy or chemotherapy, as complement of the surgical treatment.

For women, the techniques may include cryopreservation of oocytes, preservation of ovarian tissue, preservation of embryos, oocyte maturation *in vitro*, and the use of more conservative surgical techniques.

For men, the usual techniques are cryopreservation of spermatozoa and cryopreservation of testicular tissue, together with conservative surgical techniques.

Medically Assisted Procreation: Law No. 32/2006, of 26 July (amended by Law No 59/2007, of 04 September, Law No. 17/2016, of 20 June, Law No. 25/2016, of 22 August, Law No. 58/2017, of 25 July and Law No. 49/2018, of 14 August).

Clinical Recommendations for the Preservation of Fertility in Cancer Patients, available on: <https://www.spmr.pt/attachments/recom-spmr.pdf>.

iii. Right to access to health information

The right of access is carefully treated by Regulation (EU) 2016/679, of the European Parliament and of the Council, of 27 April 2016, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC. This regulation applies throughout the European Union from 25 May 2018.

The new European regime provides an obligation on Member States, in addition to the conditions applicable to special categories of data, to ensure specific guarantees for the processing of data in the field of health (Article 81). Specific conditions shall be laid down for the processing of personal data for the purposes of historical research, statistics and science (Article 83).

The Regulation gives a definition that we consider to be fairly comprehensive in terms of what we understand as personal health data.

[17] Pereira, André Dias, "Advance Directives: Binding or Merely Indicative? Incoherence of the Portuguese National Council of Ethics for the Life Sciences and Insufficiencies of Newly Proposed Regulation", in *European Journal of Health Law*, vol. 16, No. 2, 2009, pp. 165-17.

These should include in particular "all data pertaining to the health status of a data subject; information about the registration of the individual for the provision of health services; information about payments or eligibility for healthcare with respect to the individual; a number, symbol or particular assigned to an individual to uniquely identify the individual for health purposes; any information about the individual collected in the course of the provision of health services to the individual; information derived from the testing or examination of a body part or bodily substance, including biological samples; identification of a person as provider of healthcare to the individual; or any information on e.g. a disease, disability, disease risk, medical history, clinical treatment, or the actual physiological or biomedical state of the data subject independent of its source, such as e.g. from a physician or other health professional, a hospital, a medical device, or an in vitro diagnostic test".

The processing of personal health data, including genetic data, is possible provided that it is intended to fulfil one of the following purposes: preventive medicine, medical diagnosis, medical care or treatment and health service management. The processing of such data must be carried out by a health professional who is bound by confidentiality or by another person also subject to professional confidentiality, and appropriate information security measures must be guaranteed.

Personal health data relate to an identified or identifiable natural person. To this extent, these health data subjects may exercise certain rights, namely the right of rectification, the right of elimination, the right to know the purposes of the data processing and the right of access.

The patient has the right to access all health information that concerns him/ her, except in exceptional circumstances where it is unequivocally demonstrated that access to such information could seriously impair his/ her health. This health information access is carried out by the user him/ herself. Alternatively, the patient can ask the doctor that he/ she wishes to see his/ her health information.

General European Regulation on the protection of individuals with regard to the processing of personal data and on the free movement of such data: Regulation (EU) 2016/679, of the European Parliament and of the Council, of 27 April 2016.

Personal Genetic Information and Health Information: Law No. 12/2005, of 26 January.

Regulation on Conduct in Relations between Physicians, from the Order of Physicians.

Law on Access to Administrative Documents: Law No. 26/2016, of 22 August.

iv. Right to a second medical opinion

The doctor should encourage the patient to ask for a second opinion if he/ she feels useful or knows that it is the patient's will. In this case, the physician must provide all relevant information that may be used by other physicians.

However, at the level of the National Health Service, the exercise of this right is not linear, because there is not a real «second opinion» circuit or established procedure.

A second opinion can undoubtedly bring many advantages, clarifying diagnosis, identifying therapeutic options and avoiding unnecessary procedures and medical exams.

Regulation on Conduct in Relations between Physicians, from the Order of Physicians.

Rights and Responsibilities of the Health Service User: Law No. 15/2014, of 21 March.

v. Children with cancer and informed consent

Children are represented by their parents. In case of simple procedures, the accompanying parent authorization is sufficient. In case of major medical proceedings both the authorization of the father and the mother is required even if parents are not married, are separated or divorced.

After 16 years old, some special statutes also require the consent of the adolescent (v. g. clinical research act — Law 21/2014, 16 April — Art. 7 (1) (a)). The literature argues that adolescent after 16 years old should, in general, give the sole consent for medical treatments, based on International and European Human Rights Law, as well as the interpretation of article 38 of our Penal Code and with analogy with another personal decisions, v. g. marriage and religion.

vi. *Social protection / Specific benefits — Social guarantees*

Cancer patients, because of their disability status, have some specific benefits as regards social security, taxes and fees, housing loans, rental contracts and special employment regulations.

a) *Social security*

Social Security is a system that seeks to guarantee citizens' basic rights and equal opportunities, as well as to promote social welfare and cohesion for all Portuguese citizens or foreigners who work or reside in the territory.

Law No. 4/2007, of January 16, defines the general basis on which the system is founded, as well as the specific initiatives of similar ends.

The following are priority objectives of the Portuguese Social Security system:

1. Guarantee the realization of the right to Social Security;
2. Promote the sustained improvement of the conditions and levels of social protection and the reinforcement of their equity;
3. Promote the efficiency of the system and the efficiency of its management.

Protection from disease: Legal System for Social Protection from Illness — Decree-Law No. 26/2004, of 4 February; Ordinance No. 337/2004, of 31 March.

Protection from incapacity to work: General Protection System in the Event of Disability and Old Age — Decree-Law No. 187/2007, of 10 May; Legal System of Complement by Dependency — Decree-Law No. 265/99, of 14 July; Special System for Social Protection from Disability — Law No. 90/2009, of 31 August; Legal System for Social Invalidity Pension — Decree-Law No. 464/80, of 13 October.

Protection of disabled children and disabled young people: Protection regime in the event of family expenses — Decree-Law No. 176/2003, of 2 August; Legal system of family benefits — Decree-Law No. 133-B/97, of 30 May; Legal system of family benefits — Decree-Law No. 160/80, of 27 May; Regulatory Decree No. 14/81, of 7 April.

Social Provision for Inclusion: Decree-Law No. 126-A/2017, which creates the Social Provision for Inclusion.

b) *Taxes*

The basis and the main guiding principles of the Portuguese tax system are embodied in the Portuguese Constitution. Several tax benefits are provided for people with disabilities. A person is considered to have a disability when he or she has a degree of incapacity equal to or greater than 60%, according to the National Disability Table.

Income tax (individuals) — reduction in the income tax base and deductions: Individual Income Tax Code.

VAT exemptions — prostheses and cancer support products, wheelchairs, customised cars for disabled people, and others: Value Added Tax; Joint Order No. 26026/2006 of 22 December.

Tax on the purchase of vehicles for people with motor disabilities: Vehicle Tax Code

Vehicle road tax exemption: Road Tax Code.

c) *Housing loans*

Cancer patients who have a degree of disability equal to or greater than 60% benefit from subsidised conditions in granting credit for the acquisition of permanent private housing. The concession of a subsidized loan intends the construction or expansion of a permanent own housing and the credit limit cannot exceed 190.000 euros.

Scheme for granting subsidised housing loans to disabled persons — Law no. 64/2014, of 26 August.

d) *Rental contracts*

The Portuguese lease law provides that persons over 65 or disabled people cannot be forced to leave its rented house, under certain conditions, thereby benefiting from increased protection over other renters.

Cancer patients who have a degree of disability equal to or greater than 60%, have several benefits as regards rental contracts, namely in the negotiation of rent and in the termination of the contract: Urban Rental Scheme (Law 6/2006, of 27 February amended by Law 13/2019, of 12 February).

e) *Special employment regulations*

The worker with a disability or a chronic illness is equal in rights and duties to other workers in access to employment, vocational training, career development and working conditions, except as specifically concerns his or her situation.

A worker with a disability or a chronic illness may be exempted from exercising his professional activity in adaptability regime, hourly or concentrated hours regime, and may be exempted from work between 08:00 pm and 07:00 am of the following day, for their health and safety. Moreover, the worker is not obliged to work additional hours. The employer has an obligation to create the best working conditions for the disabled worker.

f) *End of life issues*

As regards the debate on end-of-life decisions, it is worth pointing out that there are some areas of consensus, notably:

- The right to refuse treatment;
- The right to painkillers/ analgesics;
- The double effect theory;
- The right to palliative care;
- The right to palliative sedation or continuous deep sedation.

The right to refuse treatment has been recognized, at least since 1982, by art. 156 of the Portuguese Criminal Code, by Law No. 15/2014 and by the Convention on Human Rights and Biomedicine (in force since 2001 in Portugal). Also, art. 5 (3) of Law N.º 31/2018, of July 18, states: "Persons

in the context of advanced disease and end-of-life, provided that they are adequately informed of the foreseeable consequences of this option by the responsible doctor and the accompanying multidisciplinary team, are entitled to refuse, under the law, artificial support of vital functions and to refuse to provide treatments that are not proportionate or adequate to their clinical condition and treatments of any nature, which do not aim solely at reducing suffering and maintaining patient comfort or which prolong or aggravate such suffering".

Art. 65 of the Regulation on Medical Ethics (Reg. No. 707/2016) consecrates the prohibition of dysthanasia, i.e. the use of all possible means, whether proportionate or not, to prolong life artificially and thus delay the advent of death in patients in the final stages of life, despite there being no hope of healing.

The right to palliative care is proclaimed in Law No. 52/2012, of 5 September — Basic Law of Palliative Care that establishes a National Network of Palliative Care — and in art. 66 of the Regulation on Medical Ethics:

> *"1 - In cases of advanced and progressive diseases where treatment does not reverse their natural development, the physician should direct his or her actions to the well-being of patients, avoiding therapeutic futility, namely the use of diagnostic and therapeutic means which can in themselves induce more suffering, without there being any benefit.*
>
> *2 - Palliative care, with the aim of minimising suffering and improving, as far as possible, the quality of life of patients, is the standard care in situations to which the previous number refers."*

By the same token, Art. 6 of Law No. 31/2018, of 18 July, provides the following rules:

> *"1 - People in advanced and end-of-life illnesses are entitled to receive palliative care through the National Health Service, within the scope and form provided for in the Basic Law on Palliative Care.*
>
> *2 - Palliative care is also considered to provide spiritual support and religious support if the patient manifests this will, as well as structured support for the family, which can be extended to the stage of mourning.*
>
> *3 - Palliative care is provided by a multidisciplinary team of duly accredited professionals and in a hospital, home or residential environment, according to the law".*

Art. 7 of the same Law provides some rights concerning palliative care at home, especially for the informal caregivers:

> *"1. Informal caregivers of the person in the context of advanced illness and end-of-life who receive palliative care in a home environment are entitled to receive adequate training and structured support provided by the State through the articulation between the Ministry of Health and the Ministry of Labour, Solidarity and Social Security.*
>
> *2. Health professionals should request the right to rest of the informal caregiver of the person in the context of advanced illness and at the end of life who is in a home environment whenever this is justified."*

In what relates with the right to avoid pain and suffering and the regulation of the deep sedation, Law 31/2018 has an important article concerning "brief vital prognosis" — Article 8. It states:

> *"1 - Persons with a life expectancy estimated in weeks or days who present symptoms of suffering not controlled by the first-line measures provided for in Article 6 (1), are entitled to receive palliative sedation with properly titrated and adjusted sedative drugs exclusively for the purpose of treating suffering, in accordance with the principles of good clinical practice and leges artis.*
>
> *2 - Persons who are in the situation described in the previous number are subject to regular clinical monitoring by teams of professionals who are properly accredited in the provision of palliative care.*
>
> *3 - The person in a situation of last days of life, the right to refuse to feed or to provide certain personal hygiene care is guaranteed, thus respecting the natural and physiological process of his clinical condition".*

Euthanasia and assisted suicide are not allowed in Portugal and are punished as a criminal offence. The Criminal Code provides attention to the diminished gravity of wrongfulness and fault in cases of homicide by request of the victim and assisted suicide. Art. 134 of the Code punishes voluntary direct euthanasia with imprisonment of up to (only) 3 years. And Art. 135 of the Criminal Code establishes the same penalty for assisted suicide. This compares with a penalty of 8 to 16 years in prison for homicide and up to 25 years in jail for murder (first degree murder). Such proceedings are thus prohibited, criminalised and subject to criminal penalties, and naturally subject to disciplinary proceedings at the Medical Association and Administrative disciplinary proceedings. However, we are not aware of any such case.

In February 2016, the Manifest "Right to die/in dignity" was issued. This document was signed by more than 100 personalities of different political backgrounds. It states: "It is imperative to put an end to unnecessary and senseless suffering imposed on behalf of other people's beliefs. (…) It is urgent to decriminalise and regulate assisted death"; "No one can force anyone to live in suffering." This is why a debate is being called on the decriminalisation of euthanasia in Portugal.

There were four drafts: from PAN (*"Pessoas Animais e Natureza"),* from "*Bloco de Esquerda*", from "*Partido Os Verdes*" and from the Socialist Party ("*Partido Socialista*"). They were rejected in May 2018 by the Portuguese Parliament (votes against from the right wing and the Communist Party), being the slightest margin of 5 votes: 110 in favour; 115 against the Socialist Party project. It is expected that in the next Parliament, there will be another debate and voting.

We will briefly outline the Left Bloc Draft-Law (that is similar to the others).

> Article 2 - On the request of anticipation of death
>
> 1. The request for anticipation of death must correspond to the free, serious and informed will of the person with definitive injury or incurable and fatal illness and in lasting and insupportable suffering.
>
> 2. The said request can only give rise

to a clinical process of anticipation of the death if it is carried out by an adult person, capable of understanding the meaning and scope of the request and aware at the time of its formulation.

3. The application can be freely revoked at any time.

This draft-law never mentions the expressions euthanasia or assisted suicide. Rather it uses the semantics of "Assisted Dying". And it does not distinguish assisted suicide from euthanasia. It aims to accept "assisted dying" for definitive injury or incurable and fatal disease with durable and unbearable suffering, including physical suffering or psychic suffering.

The "proceeding" can be performed by a medical doctor or by another healthcare professional under the doctor's supervision.

This procedure is subject to a procedural control: it requires the acceptance of two doctors and in some cases one psychiatrist if there are doubts.

The patient must be a capable adult, who makes an express and repeated request. After the procedure, there shall be a mechanism of assessment and post-control and an Evaluation Committee is provided for.

The Draft-law of the Socialist Party required a *prior* authorization of a National Committee.

vii. *Research and cancer*

a) *Status and legal aspects of biobanks in Portugal*

In Portugal, biobanks are regulated in Law No. 12/2005, of 26 January (amended by Law No. 26/2016, of 22 August). The main focus of the legislation in force is genetic and health information, the concept of health information and genetic information itself, the circulation of information and intervention in the human genome, together with some specific rules on the collection and preservation of biological products for the purposes of genetic testing or research (Article 1).

It therefore establishes guidelines on any repository of biological samples or their derivatives, with or without time-limited storage, whether using prospective harvesting or previously harvested material, obtained as a component of routine health care or in research, including samples that are identified, identifiable, anonymous or anonymised (Article 19 (1)). Under the terms and scope of this legal provision, banks of biological products must be constituted only for the purpose of providing health care, including diagnosis and prevention of diseases, or basic or applied health research.

Besides this 2005 law, we must also mention the existence of Law No. 12/2009, of 26 March (that establishes the legal regime of quality and safety related to the donation, collection, analysis, processing, preservation, storage, distribution and application of tissues and cells of human origin, transposing Directives 2004/23/EC of the European Parliament and of the Council of 31 March, 2006/17/EC of the Commission of 8 February 2006 , and Commission Decision 2006/86/EC of 24 October) and Law No. 5/2008 of 12 February (approving the creation of a database of DNA profiles for the purpose of civil and criminal identification). However, given the specificity of these laws and the subject of this report, we will not analyse them.

In turn, Law No. 12/2005 is regulated by Decree No. 131/2014, of 29 August, concerning the protection and confidentiality of information in genetics, the human genetic databases with the purpose of providing health care, and the conditions for provision and performance of genetic tests.

Finally, we should also take into account Law No. 21/2014, of 16 April (concerning clinical research as a systematic study for discovering or verifying the distribution or effect of medicines, and the security procedures in this field).

This legislation specifically refers to biobanks in Article 39(3)(g), which refers to the objectives of the National Register of Clinical Studies, namely the need to disclose public and private services to support and conduct clinical studies, as well as national resources to support research, including clinical records, biobanks, and clinical and genetic databases.

Among the most relevant elements, we should highlight the following:

A) The biological material stored in these biological product banks is owned by the persons from whom it was obtained and, after their death, by their relatives;

B) Informed consent has special requirements:

   a) The acceptance should be written, including the information on the purposes of the bank, its scope, the types of research, the conditions and duration of storage, measures to ensure privacy and confidentiality and the possibility of communication or not of results obtained from such material (Article 19 (5));

   b) There must be separate forms on informed consent depending on the use of the samples (Articles 18 and 19);

   c) The right to remove consent (by the person or his/her relatives in case of death or incapacity) regarding the storage of biological material, in which case the samples and derivatives must be definitively destroyed (Article 18, (3));

   d) Samples taken with a specific medical or scientific purpose may only be used with the express consent of the persons from whom the samples were obtained or their legal representatives (Article 18 (5));

   e) In particular circumstances where information may be relevant to the treatment or prevention of a disease in the family, that information may be processed and used in the context of genetic counselling, even if it is no longer possible to obtain consent (Article 18 (6)).

   f) All direct and second-degree relatives of the collateral line may have access to a stored sample, proving that it is necessary to gain a better understanding of their own genetic status, but not to know the situation of the person to whom the sample belongs or of other family members (Article 18 (7));

   g) In the case of retrospective use of samples, or in special situations where the consent cannot be obtained due to the amount of data or subjects, their age, or other similar reason, the material and data may be processed, but only for the purposes of scientific research, or collection of epidemiological or statistical data.

Pursuant to Article 19, it is the responsibility of the person in charge of the biobank/bank of biological products to ensure that such rights are respected. The person in charge must always verify that the rights and interests of the persons to whom the biological material belongs are duly protected, including their privacy and confidentiality (and here we must take into account what the Portuguese and European legislation on personal data states), but also regarding the preservation of samples, which may later be necessary for the diagnosis of family illness, as part of genetic testing on these persons or their relatives.

In the context of oncological diseases in Portugal there are several databases (such as the Regional Oncology Registries and, more recently, the National Cancer Registry), and also several biobanks that are relevant for the investigation of oncological diseases and assistance.

The largest national biobank is the Biobank of the Institute of Molecular Medicine (IMM) at the Faculty of Medicine of University of Lisbon. This collects and stores an assortment of biological samples, voluntarily donated, with the aim of boosting biomedical research. Currently, hundreds of thousands of samples, in particular of blood, serum, saliva, urine, bone, tissue and tumour DNA, and clinical information from thousands of donors are stored on a single platform to support research on the origin of diseases that have a huge impact on public health, such as cancer or osteoporosis. Requests for use of samples are evaluated with regard to the interest of the research project, and must be approved by the IMM ethics committee and the scientific committee to "ensure that the scientific question posed is relevant, original and not a replication." The IMM Biobank currently brings together 14 collections in areas as diverse as neurology, rheumatology, orthopaedics, oncology, cardiology and endocrinology.

There are also several Tumour Banks with repositories of biological samples from several Portuguese health units. In 2013, the Portuguese government announced its intention to set up a National Network of Tumour Banks, which would allow the standardisation of procedures for the collection and storage of biological material in these Tumour Banks. The General Directorate of Health provides the necessary requirements on its electronic platform for the constitution of Tumour Banks. It defines a Tumour Bank (BT) as a particular type of biobank consisting of the organised collection of tumour samples (neoplasms), which may comprise tissues non-neoplastic diseases. The samples stored in the BT may be constituted of fragments, cells and/or liquids, or their derivatives (DNA, RNA, proteins), regardless of how the biological samples are preserved (fixation, inclusion in paraffin, freezing). The purpose of a BT is to archive this type of material and associated information (epidemiological, clinical, anatomic-pathological and molecular), under ideal conditions for biomedical research. The availability of this type of material, when collected under optimum conditions, allows the development of translational research and the application of basic biomedical research knowledge to clinical problems.

CANCER & PERSONALIZED MEDICINE SOME (BIO)ETHICAL ISSUES

Eduardo A. da Silva Figueiredo

I. Is Personalized Medicine Redefining Cancer?

In the present times, some authors state that personalized (or precision) medicine — *id est*, the successful implementation of a new model of medicine which analyses in detail the phenotype and the genotype of the individual in order to define an appropriate therapeutic strategy (and the right moment to introduce it) and to identify the disease for which he/she is predisposed in order to define the most adequate timing and manner to prevent or mitigate it[1] — is redefining cancer.

Until recently, when someone was diagnosed with a certain type of cancer, he/she would receive an equal treatment as all the other patients who suffered from the same illness[2]. Nevertheless, we now know that different people may respond differently to the same treatment due to the fact that, during time, patients' tumours suffer some genetic changes, which will allow the cancer to grow and spread — and note that the changes that occur in one person's cancer may not exactly occur in others, even if the type of cancer is the same[3]. Because of this fact, the American Cancer Society (ACS) has already stated that "the type of cancer a person has — and how it gets treated — is no longer just about where in the body the cancer started, such as in the breast or lungs or the colon"[4]. The last decades of advances in science, technology and medicine, allowed the researchers to understand that cancer "can arise from any number of genetic malfunctions, and often is due to a combination of errors, that ultimately lead to the out-of-control cell growth that causes tumours to grow and spread"[5]. This considerable advance in the understanding of the genetic causes of cancer had a decisive role in the development of some revolutionary and targeted techniques[6], which are supposed to potentiate (or, in some cases, substitute) the so-called "classic treatments" for fighting cancer, such as radiation, chemotherapy or immunotherapy. As we will see, the fact that doctors, when they decide how to attack a cancer, take in consideration all the available knowledge about the specific molecular and genetic makeup of their patient's tumour can bring a lot of considerable advantages to the treatment, *verbi gratia*

[4] Mendes, Elisabeth, "Personalized Medicine: Redefining Cancer and Treatment", April 2015, available at: <https://www.cancer.org/latest-news/personalized-medicine-redefining-cancer-and-its-treatment.html>.

[5] *Idem*.

[6] One of the main factors which allowed the personalization of the treatment was the dawn, in the latter part of the 20th century, of the so-called "genomic age". According to Turnbull, "high-throughput technologies such as gene-expression microarrays gave researchers the opportunity to explore the underlying genetics of cancer with a high degree of detail and accuracy". See Turnbull, Arran K., "Personalized medicine in cancer: where are we today?", *op. cit.*, p. 2796.

making it safer and more effective.

Besides these facts, one must note that along with the genetic variations in tumours *per se*, some inherited genetic variants in genes that metabolize and process drugs will also influence the response to the treatment administered to the individual. In order to grant that the doctors will prescribe "the right medicine, to the right patient, at the right dose", there is a huge investment in the promising field of pharmacogenomics, regarded as the field of investigation which evaluates the relation between the genomic characteristics (identified variations) and the correspondent pharmacological relevant effects. Moreover, it studies how different genotypes can influence each individual's drug response[7].

Last but not the least, note that personalized medicine is not just relevant for cancer treatment, but also for its prevention. As stated by Mendes, "with the knowledge of the mutations linked to cancer and the access to more cost-effective genetic testing, researchers and doctors are increasingly able to identify if a person is at a higher risk for cancer and if a cancer patient is at bigger risk for getting another cancer"[8]. This way, they can properly advise the individual about the need to change his/her lifestyle (encouraging him/her to engage in risk reduction behaviours) or the environment he/she lives in or to start any kind of prevention therapy.

In short and invoking (once again) the accurate words of Mendes, when one refers to a growing personalization in cancer treatment, this might mean: "(1) testing a person's cancer to find out if a certain type of treatment will work on it; (2) looking at the person's genetics to decide whether he or she can handle a specific medicine, or (3) conducting a genetic test to determine if a person has certain genetic mutations that could put them at a higher risk for developing cancer"[9]. And there is no doubt that all this potential will (and, I dare to say, already is) redefining cancer and the way it is being treated.

II. Some Advantages of Precision Medicine

It's quite easy to understand that there is a huge potential in the personalization of the medical and pharmacological treatment according to the specificities of one's genome.

First of all, this type of approach will definitely increase the effectiveness and safety of the therapy applied to fight and, eventually, destroy the cancer — note that, according to some recent studies, only 1 in each 3 individuals is able to obtain therapeutic benefits from the prescribed drugs; in the remaining cases, either the drug doesn't produce the expected effect, or it's possible to verify the occurrence of undesired toxic side effects and other adverse drug events (ADE's). Thus, it's truly important that researchers work hard to discover a wide variety of new tactics to achieve what is now called "personalized cancer care", in order to boost the effectiveness and safety of all the treatments and therapies used[10].

[7] Note that these variants may increase the toxicity of specific drugs. See VERMA, Mukesh, "Personalized Medicine and Cancer", in *Journal of Personalized Medicine*, Vol. 2, 2012, p. 2.

[8] MENDES, Elisabeth, "Personalized Cancer Prevention", April 2015, available at: <https://www.cancer.org/latest-news/personalized-cancer-prevention.html>.

[9] MENDES, Elisabeth, "Personalized Medicine: Redefining Cancer and Treatment", *op. cit.*

[10] As stated by MENDES, "these [new tactics] include identifying as many genetic mutations as possible in different cancers, faster and more effective techniques for sequencing tumors, and new methods for more accurately matching treatments to patients and developing more targeted therapies". See MENDES, Elisabeth, "Personalized Can-

Also, one must note that the proper study of the genetic characteristics of the tumour of a specific person may allow him/her to participate in precision medicine clinical trials which test new promising treatments designed to target a specific change in the tumour[11] — and this fact permits that only the patients which are more likely to benefit from the treatment will participate in the clinical trial and reduces the number of participants that are needed (which makes it less time-consuming and less costly). Besides this, all the information gathered from the research is usually collected in databases which are accessible to scholars and scientists for further study, allowing the development of new techniques and treatments.

Another point that is worthy of being stressed is the fact that investment in precision medicine and pharmacogenomics can be, in a long-term perspective, truly beneficial — in an economic sense — for every State. When it comes to this issue, some authors argue that the cost of developing this kind of personalized treatment is a total misallocation of societal funds that are needed to satisfy other basic needs of the people. I tend to disagree with this kind of reasoning — some studies show that the cost of treating patients requiring hospitalization due to (*a posteriori*) occurrence of adverse drug events is estimated at between $1.56 billion and $5.6 billion annually, in the USA. As stated by Barash, "it is believed that many of these reactions are due to genetic variants and the hospitalization, even death, can be avoided by testing people for ADE's prior to prescribing certain drugs"[12]. Therefore, it seems that taking the individual's genetic data in consideration at the moment of prescribing him the therapy, can considerably reduce the probability of posterior occurrence of this kind of adverse events that can cost up to billions to the public budget or even lead to the loss of human lives.

Finally, one must not forget that this kind of reasoning can also be applied to insurance companies. Although we have to admit that, on the one hand, "providing healthcare is more expensive when more tests are performed to diagnose a disease and when customized treatment is used", on the other hand, "in the long term, personalized medicine will be beneficial because information about a person's disease and responsiveness to different interventions and treatment will be helpful in developing disease-prevention approaches"[13].

In short, investment in precision medicine techniques which allows the doctors to make a precise diagnosis that can avoid "unnecessary and ineffective treatments, prevent adverse events and deliver more effective targeted therapeutics" will, with no doubts, result in less costs for the payer (either the State or insurance companies) in the long term[14].

Because of these facts — and others that, *hic et nunc*, I can't address properly — researchers and doctors from all around the world are committing themselves to find new and precise techniques to fight cancer in a more effective, safer and less

cer Care: Where it Stands Today", April 2015, available at: <https://www.cancer.org/latest-news/personalized-cancer-care-where-it-stands-today.html>.

[11] Note that in order to be eligible for this kind of precision medicine trials, the tumor of the person must have a genetic change that can be targeted by the treatment being tested. See National Cancer Institute (USA), "Precision Medicine in Cancer Treatment", *op. cit.*

[12] Barash, Carol Isaacson, "Ethical Issues in Pharmacogenetics", in *ActionBioScience,* April 2013, available at: <http://www.actionbioscience.org/biotechnology/ethical_issues_in_pharmacogenetics.html>.

[13] Verma, Mukesh, "Personalized Medicine and Cancer", *op. cit.,* p. 8.

[14] *Idem*, p. 9.

costly way[15].

III. Some Bioethical Challenges

Although the personalization of the treatment has a lot of considerable advantages, one must not forget that all these techniques pose different ethical, juridical, societal and regulatory issues that, in some cases, can be seen as an impediment to its progress and implementation in the healthcare systems of the various countries. In this specific context, bioethics[16] has to work as a "traffic light", promoting the debate and defining when it's safe or not to move forward in the implementation of this kind of revolutionary techniques and policies. Let's take a look on some of the most important bioethical questions raised by personalized medicine and pharmacogenomics applied to cancer treatment.

Although personalized medicine can help to reduce costs with healthcare in the long term, there is no doubt that personalized cancer care is more expensive than the available traditional treatments, especially if we take into account the high price of the tests to which the individual must be subjected in order to define the appropriate therapy[17]. Thus, some issues about accessibility to this kind of treatments can be raised, not only relating to those individuals who wish to benefit from them but who do not have the economic means to do so, but also for some developing countries that do not have the adequate resources or specialized professionals to provide a personalized care to their people[18]. In these cases, the (huge) allocation of the necessary resources to invest in this field may result in disinvestment in other key-areas or even in the violation of human rights. Therefore, a careful discussion on the strategic planning of the health system must be called for, considering all the consequences (namely, the economic ones) of this new model of medicine. This is the only way to guarantee equity and equality in the access to healthcare.

Also, one must not forget that personalized medicine and pharmacogenomics can raise some specific problems related to the possibility of increase of genetic discrimination within the system. As stated by Romeo Casabona, genetic data has "some special characteristics" which justify its reinforced protection through law and its qualification as sensitive data[19]. But the truth is that this new individualistic medical approach requires, in order to be effective, a widespread sharing of this kind of information, which can be used, v.g., in the workplace or by insurance companies to unlawfully discriminate the worker or the insured person. Due to this fact, law must assure that "no individual or group should be discriminated against or stigmatized on any grounds, in violation of human dignity, human rights and fundamental freedoms"[20]. Last but not least, besides a proper guarantee of privacy and confidentiality of one's genetic data, law must make effective the fundamental right to informational self-determi-

15 Turnbull, Arran K., "Personalized medicine in cancer: where are we today?", *op. cit.*, p. 2796.

16 Remember that, according to Barbas, bioethics "is the interdisciplinary study of the set of conditions required for any kind of responsible life management, focusing on the study of the fast and complex advances of biomedical technologies". See Barbas, Stela, *Direito do Genoma Humano*, Coimbra: Almedina, 2007, p. 132.

17 Espinosa Brito, Alfredo, *La medicina centrada en las personas y la medicina personalizada*, Medisur, No. 6/13, 2015, pp. 922-923.

18 Romeo Casabona, Carlos, *Los Genes y sus Leyes. El Derecho ante el Genoma Humano*, Bilbao-Granada: Editorial Comares, 2002, p. 63 and ff.

19 Genetic data is known for having an involuntary, indestructible, permanent, unalterable and singular character. *Idem*.

20 Article 11 (Non-discrimination and non-stigmatization) of the Universal Declaration on Bioethics and Human Rights, UNESCO, 2005.

nation and the so-called "right not-to-know"[21], *inter alia* the results of the genetic tests.

In what concerns specifically with the bioethical issues related to the use of pharmacogenomics to fight cancer, one must take in consideration the possibility of unequal treatment of the patients, depending on how costly it is to develop and produce drugs which are, according to the characteristics of their genome, truly effective and safe. This happens because, as everybody knows, the cost-effectiveness correlation is one of the main criteria used by the pharmaceutical industry in the decision-making process of developing (or not) a specific drug. In this context, Lichtenfeld stated that "when it comes to making cancer care truly personal, drug development and testing are tricky. We are already in a situation where we know that the large majority of targets don't have a currently available drug"[22]. Efforts must be made to invert this tendency and avoid unequal and unfair treatment of the patients.

Other bioethical questions that one must stress (although I will not, *hic et nunc*, address them in detail) are: (1) the practical and economic difficulties related to the building of large-scale databases that allows the doctors to identify all the mutations on a patient's tumour and, therefore, personalize the treatment; (2) the risk that, due to the abovementioned potential of precision medicine to reduce the costs of healthcare systems, people will be pressured to undergo genetic testing before the prescription of the treatment or therapy, what can be a dangerous threat to one's autonomy and the well-known concept of informed consent[23]; (3) the possibility of racial and ethnical discrimination in the development of drugs[24]; (4) or even questions related to civil or criminal liability for the damages caused by a wrong performance of the genetic tests or by misinterpretation of its complex results[25].

IV. Will Cancer Come to an End?

Personalized medicine and pharmacogenomics will, with no doubts, redefine cancer and revolutionize the way it is treated. But one must not forget that this kind of medical approach is not "a miraculous formula" that will eradicate cancer and other diseases from our lives — fragility is inherent to human nature and will always haunt us. Moreover, if we want to "take the leap" and invest in this revolutionary field, we must previously discuss the impact that this decision will have in our lives and in every healthcare system around the world and make sure that no fundamental or human rights are harmed in the way — note, we are all stakeholders in this matter!

According to Verma, "public education and communication about personalized medicine should be part of the outreach to the population at large. Furthermore, consumers must be protected from possible harm resulting from the premature translation of research findings, and the innovative and cost-effective application of discoveries that improve personalized medical care should be en-

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[21] Loureiro, João, "Genética, moinhos e gigantes: Quixote revisitado: deveres fundamentais, sociedade de risco e biomedicina", in *Derecho y genética: un reto a la sociedad del siglo XXI* (ed. por Agustín Jorge Barreiro), Madrid: Anuario de la Facultad de Derecho de la UAM, 2006, p. 36.

[22] Mendes, Elisabeth, "Personalized Cancer Care: Where it Stands Today", *op. cit.*

[23] Lipton, Peter, "Pharmacogenetics: the ethical issues", in *The Pharmacogenomics Journal*, Vol. 3, 2003, p. 15.

[24] *Idem.*

[25] To avoid this, "doctors and primary care physicians [must try to] do their jobs better by acquiring an educational background and hands-on experience in genomic and proteomic tests and their interpretation". See Verma, Mukesh, "Personalized Medicine and Cancer", *op. cit.,* p. 9.

couraged"[26]. These are some examples of measures that should be taken in order to ensure that the leap to the wonderful world of the "medicine of the future" is going to be given safely and that no one is in danger of falling. And, believe me, if the debate on this topic is not carried out in a serious and responsible way, someone will be left behind… and we definitely don't want that to happen.

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[26] *Idem*.

WHITE BOOK ON CANCER PATIENTS' RIGHTS • SPAIN

Elena Atienza Macías / Javier García Amez / Isabel Gil Aldea

[1][2][3]

I. Introduction. Cancer Patients' rights: an overview

The life expectancy of cancer patients is somewhat higher than five years ago and considerably more than ten years ago. Even though it still constitutes the second cause of death in Spain (behind cardiovascular diseases), being the five-year survival rate in Spain is 61.5%[4]. The burgeoning field known as Personalized Medicine, the development of new predictors of efficacy and toxicity as well as the possibility of new treatments could increase this life expectancy in the coming years. Therefore, it is essential to ensure the quality of life of cancer patients or of those who have suffered this disease in the past.

In recent years, there has been a change in the attitude towards cancer, which has ceased to be perceived as a necessarily fatal disease but much work remains to be done regarding cancer patients' rights.

Along with oncological research and the information that is transmitted in terms of prevention, epidemiology or new treatments — which should always be based on scientific evidence —, it is important to build awareness about the consequences of cancer in the patients' lives and to emphasis on their rights.

In this sense, certain associations of cancer patients, in the case of Spain, *the Spanish Association against Cancer* (AECC)[5], has provided a major contribution to the development of manifestos and decalogues written by and for patients, although also directed to the society in general and to public administrations and institutions, in particular. These manifestos refer to several aspects related to this disease.

Some of the most relevant are briefly summarized below:

- The appropriate treatment for cancer.
- The need for quality contrasted information provided by medical professionals directly to patients
- The right to a prompt and accurate diagnosis of the disease, performed by a qualified expert doctor, through the necessary diagnostic tests.
- The appropriate doctor-patient relation, based on a mutual respect and trust.
- The knowledge of all available treatment options.
- The decision-making taking into account the opinion of the patient, always support-

[5] Available at: <https://www.aecc.es/Paginas/PaginaPrincipal.aspx>.

ed by the full knowledge of all options and their possible consequences.
- The access to the best available treatment, without discrimination according to economic aspects, place of residence or hospital where it is treated, being applicable to both oncological treatments and to support therapies.
- The abolition of social or labour discrimination and social assistance and/or psychological assistance of patients to the extent necessary.
- The patient access to knowledge of their basic rights and the possibility to exercise them under the protection of a legal framework.

All these aspects highlight the current need for policies that place patients and their rights at the centre of oncological care and that work in the establishment of care plans aimed at the needs of cancer survivors, which increase more each day.

The existing documentation in relation to rights — and also regarding the patients' duties —, both in the Spanish and international scene, can be summarized in a series of laws and declarations (that is to say, intentions or a series of norms and principles that the States create and *commit* themselves to fulfil within their nations. The States that sign them do not oblige themselves to comply).

i) National legislation

- Royal Decree 124/2007, of 2 February, regulates the Spanish National Register for Advance Decisions (RNIP) and the corresponding automated personal data file. (Official State Gazette issue No. 40 of 15.02.2007, pages 6591-3).
- Act 16/2003, of 28 May, on Cohesion and Quality of the National Health System (Official State Gazette issue No. 128 of 29.05.2003, pages 20567-88).
- Act 41/2002, of 14 November, governing patient autonomy and the rights and obligations concerning clinical information and documentation. (Official State Gazette issue No. 274 of 15.11.2002, pages 40126-40132).
- The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine. (Official State Gazette issue No. 251 of 20.10.1999, pages 36825-36830).
- Act 14/1986 of 25 April, known as the General Health Act (Official State Gazette issue No. 102 of 29.04.1986, pages 15207-24).
- Act 39/2006, of 14th December, on the Promotion of Personal Autonomy and Care for Dependent Persons. (Official State Gazette issue No. 299 of 15.12.2006).

ii) Declarations

a) *National*

- Decalogue of patients.
- Barcelona Declaration on Patient Associations 2003.
- Charter of Rights and Duties of Patients and Users of the Health System of the Community of Madrid, of July 29, 2004. (Office of the Patient Advocate of the Community of Madrid).

- Decalogue of patients with lymphoma (Spanish Association for Lymphoma, Myeloma, and Leukaemia patients or AEAL).

b) ***International***

- Joint Declaration on The Promotion and The Enforcement of Cancer Patients' Rights. Approved by the Association of European Cancer Leagues (ECL) in Oslo on June 28th 2002. *Declaración conjunta sobre la promoción y cumplimiento de los derechos de los pacientes de cáncer* (Spanish version).
- European Guidelines for Cancer Patients' Rights. Edited by the ECL's European network on patients' and health professionals' rights and duties Athens, 16th October 2004. *Derechos de los Pacientes: directrices europeas* (Spanish versión).
- The Cancer Survivors' Bill of Rights written in 1988 and revised for National Coalition for Cancer Survivorship (NCCS), USA, in 1999 by the late Natalie Davis Spingarn. *Declaración de Derechos de los Supervivientes de Cáncer* (Spanish version).
- Charter of lung cancer patients' rights Global Lung Cancer Coalition (GLCC), 2002. *Carta de Derechos de los Pacientes de Cáncer de Pulmón, Coalición Mundial Contra el Cáncer de Pulmón, 2002* (Spanish version).
- World Summit Against Cancer for the New Millennium. Charter of Paris: 4 February 2000 (UNESCO).
- A declaration on the promotion of patients' rights in Europe. European consultation on the rights of patients Amsterdam 28-30 March 1994 (World Health Organization).
- European Charter of Patients' Rights. Basis Document (Rome, November 2002).

II. General Principles and Health Policies

General principles on health assistance for patients with cancer are established on several Acts that regulated the access to health care and medicines (Spanish Act 14/1986, of 26th April on Health and Act 16/2003 on Coordination and quality on Spanish health system and development by several degrees 1192/2012, of 3th of august about the condition of health care benefices).

The general principles of health policies are:

- Article 43 of Spanish Constitution: recognizes the right to the health care assistance as a general principle that is binding to every public power in the framework of the Principles governing Economic and Social Policy.
- Article 148 of Spanish Constitution: The Autonomous Communities may assume competences over social assistance (ap. 21) and health and hygiene (ap. 22).
- Article 149 of Spanish Constitution: The State holds exclusive competence over external health measures; bases and general coordination of health matters; legislation on pharmaceutical products (ap. 26).

i) The Spanish national health system

The Spanish National Health System is the agglomeration of public health services that has existed in Spain since it was established through and structured by the General Health Law of 1986. Management of these services has been progressively transferred to the distinct autonomous communities of Spain that today are assumed by all the autonomous communities that have development

their own health services. The Spanish National Health System is the agglomeration of the autonomous health services and the State national service. The characteristics of the Spanish National Health System are:

- Extension of services to the entire population.
- Adequate organization to provide comprehensive health care, including promotion of health, prevention of disease, treatment and rehabilitation.
- Coordination and, as needed, integration of all public health resources into a single system.
- Financing of the obligations derived from this law will be met by resources of public administration, contributions and fees for the provision of certain services.
- The provision of a comprehensive health care, seeking high standards, properly evaluated and controlled.

All citizens have access to the country's universal healthcare system. It covers most healthcare free of charge. Foreigners also have the right to access NHS services if they're working in Spain or if they're over the retirement age. Undocumented immigrants have the right to treatment if they enter an emergency room or they are minors or women on pregnancy.

ii) The autonomous health system concerning cancer patients' rights

The existing documentation in relation to rights — and also regarding the patients' duties —, in the autonomous scene, can be summarized in a series of laws, decrees and orders, which refers to the following one:

a) ***Autonomous Law***

i. ***Andalusia***

- Law 11/2007, of 26 November, regulating genetic counselling, protection of the rights of persons undergoing genetic analysis and human DNA banks in Andalusia (Official Gazette of the Regional Government of Andalusia No. 246, of 17 December 2007, pp. 21-8).
- Order of 24 August 2004, implementing Decree 127/2003, of 13 May, establishing the exercise of the right to a second medical opinion in the Andalusian Public Health System (Official Gazette of the Regional Government of Andalusia No. 173, of 3 September 2004, pp. 19756-8).
- Decree 238/2004, of 18 May, regulating the Register of Anticipated Vital Wills in Andalusia. (Official Gazette of the Regional Government of Andalusia No. 104, of 28 May 2004, pp. 12259-61).
- Law 5/2003, of 9 October, on the declaration of anticipated vital will. Autonomous Community of Andalusia (Official State Gazette No. 279, of 21 November 2003, pp. 41231-34).
- Decree 127/2003, of 13 May, establishing the exercise of the right to a second medical opinion in the Andalusian Public Health System. (Official Gazette of the Regional Government of Andalusia No. 102, of 30 May 2003, pp. 11625-7).

ii. ***Aragon***

- Act No. 10/2011 of 24 March 2001 on the rights and guarantees of the dignity of the person in the process of dying and death.

- Law 6/2002, of 15 April, on Health in Aragon (Official State Gazette No. 121, of 21 May 2002, pp. 18061-79).

iii. ***The Balearic Islands***

- Decree 58/2007, of 27 April, extending the Law on Advance Directives and the Register of Advance Directives of the Balearic Islands (in Catalan version). (Official Bulletin of the Balearic Islands No. 70, of 10 May 2007, pp. 710).
- Decree 83/2006, of 22 September, on guarantees of maximum response times in programmed specialized and non-urgent health care in the Health Service of the Balearic Islands (in Catalan version). (Official Bulletin of the Balearic Islands. No. 136, of 28 September 2006, pp. 6-9).
- Law 1/2006, of 3 March, on advance directives (Official State Gazette No. 81, of 5 April 2006, pp. 13198-200).
- Law 5/2003, of 4 April, on the Health of the Balearic Islands (Official State Gazette No. 110, of 8 May 2003, pp. 17438-55).

iv. ***Canary Islands***

- Decree 13/2006, of 8 February, which regulates the anticipated manifestations of wills in the health field and the creation of their corresponding register (Official Bulletin of the Canary Islands No. 43, of 2 March 2006, pp. 4296-4301).
- Law 11/1994, of 26 July, on the Health Organization of the Canary Islands. (Official Bulletin of the Canary Islands No. 96 of 5 August 1994, pp. 1241 and following).
- Order of 28 February 2005, approving the Charter of Rights and Duties of Patients and Healthcare Users and regulating its dissemination. (Official Bulletin of the Canary Islands No. 55, 17 March 2005, pp. 4338-41).
- Correction of material errors of the Order of 28 February 2005 (Official Bulletin of the Canary Islands No. 73, of 14 April 2005, pp. 6184).

v. ***Cantabria***

- Order SAN/27/2005, of 16 September, establishing the standard document of wills expressed with previous character of Cantabria (Official Bulletin of Cantabria No.188, of 30 September 2005, pp. 10485-6).
- Decree 139/2004, of 5 December, which creates and regulates the registry of Prior Wills of Cantabria. (Official Bulletin of Cantabria No. 248, of 27 December 2004, pp. 12419-20).
- Law 7/2002, of 10 December, on the Health Organisation of Cantabria (Official State Gazette No. 6, of 7 January 2003, pp. 551-77).

vi. ***Castile and León***

- Law 8/2003, of 8 April on the rights and duties of persons in relation to health. Regional Government of Castile and León (Official State Gazette No. 103, of 30 April 2003, pp. 16650-9).

vii. ***Castile-La Mancha***

- Decree 10/2006, of 31-01-2006, on maximum response times and guaranteed benefits in specialized health care in Castile-La Mancha (Official Journal of Castile-La Mancha No. 25, of 3 February 2006, pp. 2113).

- Decree 8/2005, of 25-01-2005, modifying Decree 9/2003, of 28-01-2003, on maximum response times, guaranteed benefits, tariffs and payment for travel expenses in specialized health care in Castile-La Mancha (Official Journal of Castile-La Mancha No. 20, of 28 January 2005, pp. 1291).
- Decree 15/2006, of 21-02-2006, of the Castilla-La Mancha Register of Anticipated Wills (Official Journal of Castile-La Mancha No. 42, of 24 February 2006, pp. 4429-36).
- Decree 180/2005, of 02-11-2005, on the right to a second medical opinion. (Official Journal of Castile-La Mancha No. 223, 07-11-2005, pp. 19625-27).
- Law 6/2005, of 7 July, on the Declaration of Anticipated Wills regarding one's own health (Official State Gazette No. 203, of 25 August 2005, pp.29509-11).
- Law 24/2002, of 5 December, on guarantees in Specialised Health Care. Castilla-La Mancha (Official State Gazette No. 24, of 28 January 2003, pp. 3448-9).
- Law 8/2000, of 30 November, on the Health Regulations of Castile-La Mancha (Official State Gazette No. 50, of 27 February 2001, pp. 7296-7315).

viii. ***Catalonia***

- Decree 125/2007, of 5 June, regulating the exercise of the right to obtain a second medical opinion (Official Journal of the Generalitat de Catalunya No. 4899 of 7 June 2007, pp. 19369-71).
- Decree 175/2002, of 25 June, regulating the Register of Anticipated Wills. (Official Journal of the Generalitat de Catalunya No. 3665, 27 June 2002, pp. 11616).
- Law 21/2000, of 29 December, on the rights to information relating to health, patient autonomy and clinical documentation. Catalonia (Official State Gazette No. 29, 2 February 2001, pp. 4121-25).

ix. ***Valencian Community***

- Order of 25 February 2005, of the Health Ministry, implementing Decree 168/2004, of 10 September, of the Consell de la Generalitat regulating the Document of Anticipated Wills and creating the Centralised Register of Anticipated Wills (Official Journal of the Generalitat Valenciana No. 4966, of 15 March 2005 (electronic edition)).
- Decree 168/2004, of 10 September, regulating the Document of Advance Directives and creating the Register of Advance Directives of the Valencian Community. (Official Journal of the Generalitat Valenciana No. 4846, of 21 September 2004 (electronic edition)).
- Law 1/2003, of 16 January, of rights and information to the patient of the Valencian Community (Official State Gazette No. 48, of 25 february 2003, pp. 7587-95).

x. ***Extremadura***

- Decree 311/2007, of 15 October, which regulates the content, organization and operation of the Register of Advance Expression of Will of the Autonomous Community of Extremadura and creates the Automated File of personal data of the Register (Official Journal of Extremadura No. 121, of 18 October 2007, pp. 16210-8).

- Decree 132/2006, of 11 July, reducing waiting times in certain specialities in specialised health care (Official Journal of Extremadura No. 84, 18 July 2006, pp. 12830-1).
- Decree 6/2006, of 10 January, regulating the procedure and requirements for reimbursing expenditure on pharmaceuticals, orthoprosthetics and health care, as well as travel and accommodation allowances (Official Journal of Extremadura No. 7 of 17 January 2006, pp. 826-31).
- Corrigendum to Decree 6/2006 (Official Journal of Extremadura No. 9 of 21 January 2006, pp. 1031).
- Law 1/2005, of 24 June, on response times in specialized health care of the public health system of Extremadura (Official State Gazette No. 180, de 29 de julio de 2005, pp. 26890-4).
- Law 3/2005, of 8 July, on health information and patient autonomy (Official State Gazette No. 186, of 8 August 2005, pp. 27513-24).
- Decree 16/2004, of 26 February, regulating the right to a second medical opinion within the scope of the Public Health System of Extremadura (Official Journal of Extremadura No. 26, of 4 March 2004, pp. 2356-8).
- Law 10/2001, of 28 June, on Health in Extremadura (Official State Gazette No. 177, of 25 July 2001, pp. 27021-39).

xi. ***Galicia***

- Decree 205/2007, of 27 September, regulating the right to a second medical opinion in the Galician public health system (Official Gazette of Galicia No. 215, 7 November 2007, pp. 17804-8).
- Decree 104/2005, of 6 May, guaranteeing maximum waiting times in health care (Official Gazette of Galicia No. 90, 11 May 2005, pp.7902-6).
- Law 3/2005, of 7 March, amending Law 3/2001 regulating informed consent and the clinical history of patients (Official State Gazette No. 93, 19 April 2005, pp. 13364-8).
- Law 3/2001, of 28 May, regulating informed consent and the clinical history of patients. Autonomous Community of Galicia (Official State Gazette No. 158, de 3 de julio 2001, pp. 23537-41).

xii. ***La Rioja***

- Order 8/2006, of 26 July, of the Ministry of Health, on the way to grant document of previous instructions before personnel of the administration (Official Bulletin of La Rioja No. 103, of 5 August 2006, pp. 4760 (electronic edition)).
- Decree 30/2006, of 19 May, regulating the Register of Prior Instructions of La Rioja (Official Bulletin of La Rioja No. 69, of 25 May 2006, pp. 3101 (electronic edition)).
- Law 9/2005, of 30 September, regulating the document of prior instructions in the field of health (Official State Gazette No. 252, of 21 October de 2005, pp. 34392-5).
- Law 2/2002, of 17 April, on Health in La Rioja (Official State Gazette No. 106, of 3 May 2002, pp. 16210-37).

xiii. ***Madrid***

- Order 2191/2006 of 18 December, which

develops Decree 101/2006 and establishes the official models for the documents requesting the registration of prior instructions and their revocation, modification or substitution (Official Bulletin of the Community of Madrid No. 302, of 20 December 2006, pp. 28).

- Decree 101/2006, of 16 November, of the Governing Council, regulating the Register of Prior Instructions of the Community of Madrid (Official Bulletin of the Community of Madrid No. 283, of 28 November 2006, pp. 37-39).
- Law 3/2005, of 23 May, regulating the exercise of the right to formulate prior instructions in the health field and creating the corresponding register (Official Bulletin of the Community of Madrid No. 140, 14 June 2005, pp.4-6).
- Law 12/2001, of 21 December, on the Health Regulations of the Community of Madrid (Official State Gazette No. 55, of 5 March 2002, pp. 8846-81).

xiv. ***Murcia***

- Decree 71/2007, of 11 May, establishing the exercise of the right to a second medical opinion in the public health network in the Region of Murcia (Official Bulletin of the Region of Murcia No. 116, 22 May 2007, pp. 15388- 9).
- Decree no. 25/2006, of 31 March, which develops the basic state regulations on information on waiting lists and establishes the necessary measures to guarantee a maximum time of access to the benefits of the public health system of the Region of Murcia. (Official Bulletin of the Region of Murcia No. 82, of 8 April, pp. 10967-70).
- Decree no. 80/2005, of 8 July, which tests the regulation of prior instructions and their registration (Official Bulletin of the Region of Murcia No. 164 of 19 July, pp. 17253-57).
- Annex to Decree 80/2005 - Model application for registration in the Register of Prior Instructions of the Region of Murcia (Official Bulletin of the Region of Murcia No. 178 of 4 August, pp. 18268).

xv. ***Navarre***

- Foral Decree 140/2003, of 16 June, which regulates the Register of Anticipated Wills (Official Bulletin of Navarre No. 81, of 30 June 2003).
- Foral Law 29/2003, of 4 April, partially modifying Foral Law 11/2002 of 6 May on patients' rights to advance directives, information and clinical documentation. Government of Navarre (Official State Gazette No. 120, de 20 de mayo 2003, pp. 19106-7).
- Foral Decree 241/1998, of 3 August, on personalised care and follow-up in specialised health care and choice of specialist doctor by the primary care doctors of the Navarre Health Service — "Osasunbidea" (Official Bulletin of Navarre No. 105 of 02-09-1998).

xvi. ***Principality of Asturias***

- Act 7/2019, of 29 March, of Health. (Official Bulletin of the Principality of Asturias No. 71, of 11 April 2019).
- Act 5/2018, of 22 June on Rihts and Guar-

anty of Persons Dignity at the End of the Life Process (Official Bulletin of the Principality of Asturias No. 154, of 4 July 2018)
- Decree no. 51/2019, of 21 June on clinical record and other clinical documents (Official Bulletin of the Principality of Asturias No. 130, of 8 July 2019).
- Decree no. 4//2008 of 23 January, which tests the regulation of prior instructions and their (Official Bulletin of the Principality of Asturias No. 31, of 7 February 2008 pp. 2353-9).

xvii. ***Basque Country***

- Order of November 6, 2003, of the Department of Health by which the automated data file of personal data called "Basque Register of Anticipated Wills" is created and added to those managed by the Department of Health (Official Gazette of the Basque Country No. 250ZK, of 23 December 2003, pp. 24869-73).
- Decree 270/2003, of 4 November, of the Basque Government, creating the Basque Register of Anticipated Wills (Official Gazette of the Basque Country No. 233ZK, 28 November, pp. 23021-33).
- Law 7/2002, of 12 December, on advance directives in the field of health. Government of the Basque Country (Official Gazette of the Basque Country No. 248, of 30 December 2002, pp. 23318-23).

iii) ***The autonomous health system concerning cancer patients' rights. Special reference to the Basque Autonomous Community: the case of "Osakidetza" — Basque Health Service***

a. Axes of Basque health policy regarding patients with cancer

For the Department of Health of the Basque Government and "*Osakidetza*" — Basque Health Service, tackling cancer, the main cause of death in the Basque Country, has been a priority. Since the year 2000 there has been a generalized and significant increase in the survival of cancer in the Basque Autonomous Community with rates that exceed those of the State and the European Union, but it is only the consequence of the firm commitment of the Basque Government to maintain a universal, quality public health system.

In this sense, an instrument that has recently been approved is the Basque Country Oncology Plan 2018-2023[6]. Its aim is to continue improving results and to have a defined and structured strategy in the Basque Country to respond to the needs of all people who suffer and will suffer from this disease in the future, and it would highlight among its objectives the reduction of mortality and improvement of quality of life. Thanks to advances in early diagnosis, personalised therapies, new treatments, research and the constant effort and involvement of the "*Osakidetza*" — Basque Health Service professionals, it can be said that cancer has often become a chronic disease and currently a high percentage of patients have prolonged survival.

The Department of Health of the Basque Government is committed to quality oncological patient care, a comprehensive approach and personalised treatment, maintaining and reinforcing prevention policies and screening programmes, from an intersectoral perspective, because it constitutes an investment to achieve, in conditions of

[6] The Basque Country Oncology Plan 2018-2023 is available at: <http://www.euskadi.eus/contenidos/informacion/plan_oncologico_2018_2023/es_def/adjuntos/plan-oncologico-euskadi-2018-2023-10-13.pdf>.

equality, higher levels of health and well-being. However, if there is one thing that characterises this Oncology Plan, it is undoubtedly that it puts the patient at the centre, both in the healthcare model, in innovation and in research, as well as when it comes to establishing preventive measures. The core element of the Plan is the needs of the person with cancer throughout the entire process, both physical and emotional, and in providing a comprehensive response from a multidisciplinary point of view. The proposal is to continue to delve into oncological care from a human perspective, in which the patient also participates in decision-making.

This is the essence of this document, aligned with the principles that inspire the Health Plan 2013-2020 and which defines action in oncology care over the next five years in the following areas: intersectoral action, the healthcare model, information systems, precision medicine, and research and innovation.

b. Health plan 2013-2020 in the Basque Autonomous Community

The Basque Country Health Plan includes a wide range of actions and objectives to be achieved in the field of cancer. A set of diseases that are the leading cause of death in the population of the Basque Autonomous Community. For this reason, the starting point for reflection is made up of different aspects of intersectoral action and measures in health promotion and prevention that are intimately related to the genesis of cancer, to later focus specifically on the problems it causes in the people who develop it.

In this sense, the Basque Oncology Plan defines the fields of action in oncology care to operationalize the intervention elements present in the 2013-2020 Health Plan. In this sense, in accordance with the principles that inspire the Health Plan, the intersectoral strategies of health promotion that they pursue have an enormous relevance in the strategies of intervention against cancer:

- Minors should not start drinking alcohol or should do so as late as possible because alcohol is a risk factor for cancer.
- Smoking cessation as a health problem associated with cardiovascular disease but also with cancer (lung and bladder e.g.).
- Physical activity, vaccination against hepatitis B and human papillomavirus (HPV), sun protection and other strategies to promote healthy lifestyles that form the basis for preventing as much as possible cancer in its different forms.
- Workplaces are safe environments, where exposure to carcinogens is prevented.

This Plan is articulated for its development on three key and interdependent elements[7]:

- It is based on an Assistential Model that from an equity perspective offers quality services from the community (health promotion), preventive, diagnostic and therapeutic points of view. To advance the quality and responsiveness of the health care system, the Plan addresses two issues of special importance in relation to the ability of the health system to organize itself in a way that guarantees the best health outcomes for:

[7] This Plan is articulated for its development on three key elements as indicated in <http://www.euskadi.eus/contenidos/informacion/plan_oncologico_2018_2023/es_def/adjuntos/plan-oncologico-euskadi-2018-2023-10-13.pdf>.

- Reduce cancer diagnosis and treatment times;
- To concentrate the treatment of relatively infrequent cases of cancer or in those in which the result is conditioned by the volume of cases that are attended. Advance also in the capacity to offer organisational models that allow optimum use to be made of all the assistive devices in oncology without affecting the nature of the institutions on which these devices depend.

- Another fundamental element upon which the Plan is based must be an *Information System* capable of identifying the needs of people with cancer and evaluating health outcomes. Two lines of action define action in the short and medium term. On the one hand, it is a question of developing an information system that complements the current cancer registry in the Basque Country. Undoubtedly one of the best registers in Europe, but with the challenge of integrating with the electronic Clinical History to offer information in real time that supports the actions of evaluation and decision making in oncology. This development will make it possible to open up new lines of research capable of placing the Basque Country at the forefront of Europe in this field. On the other hand, from the perspective of paying for the health results of drugs that if they are not capable of offering good results may jeopardise the sustainability of the system, it is necessary in this line, to develop systems that allow measuring the health results that a certain drug has been able to offer to each patient. Results both in terms of effectiveness on morbidity and mortality and in efficiency of the system as a whole, as well as in other relevant results for patients related to emotional aspects and quality of life, serving as a reference for financing based on results.
- In recent years, hand in hand with technological advances and especially genomics, the concept of *Personalized Precision Medicine* (PPM) or genomics arises as a result of a health system capable of offering people individualized treatments depending on the characteristics of the person and the disease he or she suffers from. In the case of oncology, according to the molecular characteristics of the cancer a person suffers, it is possible to offer the treatment that best suits their characteristics. The development of a precision medicine must be parallel to that of the two axes of action described above. Advancing in the molecular diagnosis of cancers and depending on the type of cancer, offering the person with cancer the treatment alternative that best suits his or her circumstances is one of the imperatives of an effective healthcare system.
- Complementing the above, the deployment of a *Research and Innovation Strategy* well established in the previous lines of action can be considered as an opportunity in the context of a healthcare system capable of accompanying Basque technological companies in the development of new tools in cancer diagnosis and treatment in accordance with the RIS-3 strategy (research and innovation strategies for intelli-

gent specialisation).

Therefore, a Plan for people with cancer, centred on the physical and emotional needs of these people, in which emphasis is placed on the humanisation of oncological care as a central element around which intervention strategies are deployed in the following axes of action: 1. intersectoral action 2. the care model 3. information systems 4. precision medicine 5. research and innovation. In short, a strategic approach that is detailed in the following pages, centred on the needs of the person with cancer and from which the action axes and objectives of the Plan mentioned are derived.

c. Basque Country oncology plan 2018-2023, its basic lines

The Basque Country Oncology Plan 2018-2023[8] defines the fields of action in oncology care and aims to improve cancer survival, one of the main health problems of our society. The document, which is aligned with the principles that inspire the Basque Health Plan 2013-2020, has been drawn up by the Basque Government›s Department of Health with the advice of groups of experts and health professionals involved in the care of oncological patients and their families.

In general terms, the Plan proposes an assistance model, with a multidisciplinary approach, a humanised treatment that meets the global needs of patients and reduces diagnostic times and concentrates the most complex interventions in reference units that allow the necessary experience to be gathered.

The Oncology Plan also deepens the development of personalized or precision medicine which allows the patient to offer an individualized treatment depending on their characteristics and those of the tumour they suffer, with the support of a computer system that includes in the Electronic Medical Record all the information of the oncology process, from the treatments received to the quality of life of the patient, so that it can be useful in decision making.

All this is accompanied by the deployment of an innovation strategy that seeks to involve Basque technological companies in the development of new tools for cancer diagnosis and treatment, and a permanent commitment to intersectoral strategies for health promotion and prevention.

d. Basque Country cancer registry

The creation of the Basque Country Cancer Registry 25 years ago was undoubtedly a landmark decision as the indicators provided by this Registry have enabled decision-making as regards the breast and colorectal cancer screening programmes that have been launched over the past years and the establishment of targets for the successive health plans.

In 2006, 11,149 new cases of cancer were diagnosed for the first time, and 5410 people died as a result of this disease. This incidence of cancer in the Basque Country makes it one of the region's main health problems and therefore one which requires a significant effort for its control.

The original decision to establish the Registry was significant as, although some population-based cancer registries already existed in Spain, they tended to be based on a single province, with fewer than a million inhabitants, and this project was intended to have a much wider coverage, namely the whole autonomous Community, with all the complexity that entails. Indeed, the Basque Country Cancer Registry remains the most extensive of its kind in Spain.

During this period, we have also seen that the

problem represented by cancer at that time has increased significantly. It is well known that age is an important risk factor, and the Basque population has aged to such an extent over this period that people over 65 now account for 18.6% of the population, compared to only 10.4% in 1986.

Concerning the specific details[9] of the Basque Country Cancer Registry[10] it is worth noting that it was created in 1986, and during these past 25 years it has fulfilled one of its initial goals, namely to regularly publish cancer incidence figures for the Autonomous Community of the Basque Country (ACBC). Since its creation it has participated in numerous activities with national and international registries. The present monograph concerning cancer in the Basque Country presents the most recent incidence (2002–2006) and mortality figures (2004–2008). Furthermore, the survival after five years of follow-up (2000–2004) and evolution over the whole period studied are presented for the first time. The crude incidence and mortality rates are also calculated, as are the European and world age-standardised rates, by sex, age group, location and province, using the direct method. The Kaplan--Meier method has been used to estimate the observed survival (OS) for adults aged 14 years or older, and the Estève method to calculate relative survival (RS). The loglinear regression model is used to assess the change in these rates with time, thus allowing the annual percentage change and any inflexion points to be determined. The mean number of new cases diagnosed in the ACBC over the period studied was 11,229, with a European agestandardised incidence rate of 524.8/100,000 for men and 279.7/100,000 for women (a male to female ratio of 1.7). The most common tumour sites were the prostate (21.3%) and lung (14.7%) in men and the breast (27.2%) and colon (9.4%) in women.

The mean annual malignant tumour-related mortality rate was 3490 for men and 1962 for women in the period studied, with a European age--standardised mortality rate of 247.5/100,000 for the former and 102.3/100,000 for the latter. Malignant lung tumours accounted for 25% of the cancer-related mortality in men, followed by colon cancers (9.6%), whereas breast (15%) and colon (10.7%) cancers were responsible for the largest number of deaths amongst women. The five-year relative survival for all malignant tumours diagnosed in the ACBC was 54.1% (50% for men and 60.1% for women) over the period studied. Survival was highest in 15-44 years age group and for those tumours found to be localised at diagnosis. The RS for testicular, prostate, thyroid and breast cancer, melanoma of the skin and Hodgkin's lymphoma was higher than 80%. The study of the evolution of the incidence, mortality and survival rates showed that the incidence increased in both men and women and then subsequently stabilised. A decrease in the cancer-related mortality rates was observed for both men and women. The five--year relative survival has increased in both men (by 17 percentage points) and women (12 points) since the creation of the Basque Country Cancer Registry. Thus, it has increased from 32.9% to 50% in the final period studied for men, and from 48.1% to 60% for women. The most important cancer-related finding is the size of the incidence rate, especially for men, which contrasts with the lower mortality rate. No major interprovincial differences were observed, although the decrease in

[9] For more information, see: <https://www.osakidetza.euskadi.eus/contenidos/informacion/estado_salud/es_5463/adjuntos/cancer.pdf>.

[10] The Basque Country Cancer Registry is referenced in: <http://redecan.org/es/page.cfm?id=99&title=registro-de-cancer-de-euskadi>.

mortality, and its effect on the survival, should be noted. The survival, which is calculated here for the first time, is of particular interest when studied for specific tumour sites due to the different diseases concerned, each of which has its own aetiology, diagnosis, treatment and prevention. The analysis of the change in rates with time highlights those tumours which could pose a public health problem and which, on occasions, may be susceptible to specific interventions.

III. Subjective Rights of Patients

The protection of patients' rights recognised in the current Spanish legal framework is one of the greatest guarantees of quality healthcare and compliance with one of people's basic rights, that of health.

This legal framework also includes the duties that every patient has and that it is equally important for them to know. The aim is that the relationship with both professionals and health institutions is effective in achieving the ultimate goal that is none other than to prevent, protect and promote the health and quality of life of the patient.

i) *Evolution of the patient's role*

The role of the patient, as well as the way in which they relate to health professionals and participate in the decision-making process regarding her/his illness, has changed over the last few decades. This evolution, which still continues, is affecting both the patients themselves and the professionals and the different health institutions that make up our health system.

Thus, the patient, who was traditionally considered the recipient of the decisions that the doctor made unilaterally for the treatment of his/her illness, has become, over the years, an agent with well-defined rights and with a wide capacity to decide on the diagnostic tests and treatments he/she receives. From a mere spectator, he/she has become -in many cases- co-responsible for the decisions that have to be made throughout the whole process about his/her illness.

On the other hand, the doctor has become a consultant for his patients, to whom he/she now offers his/her knowledge and advice, but whose decisions are not imposed, but are made jointly with the patient.

As a consequence of the change in roles, health relations have gone from being vertical to horizontal, collective relations -with the entry on stage of multiple health professionals- and adapted to the type of relations characteristic of the current society in which we live.

And in this evolution, it has played a fundamental role that the patient today is more and more informed about his/her illness as well as the therapeutic alternatives and the health services made available to him/her.

In this sense, and although it depends on different factors including the pathology in question, health administrations are now aware that the well-informed patient brings many benefits to all parties involved in the process of their disease, and are beginning to become aware of the need to inform and train the patient in dealing with health professionals to overcome their fears and communicate effectively with them. The more information the patient has, the better the treatment, the better he or she faces his or her illness and understands the indications of the doctor and the healthcare professionals who treat him or her.

To this fact, we must add that there is a greater demand for information on the part of all people, so that, in addition to the patients themselves,

their relatives, friends and close people participate in the process of the disease. This is of great benefit to the patient because it helps him or her to better understand and manage his or her illness.

This increase in the level of information has also led to an increase in the number of patient associations in Spain, to which has access (in addition to patients and their families) everyone who wants to know something about a disease, even if they do not suffer from it.

ii) ***The rights of the patient***

We can all be patient at any time in our lives. Strictly speaking, however, a patient is a person who suffers physically and bodily, and especially one who is under medical care. Also defined as a patient is a person who is or will be medically recognized.

The role of the patient is included in the Spanish legislation, recognizing a series of rights and duties. According to this legislation, the patient has the right to receive comprehensive health care for his/her health problems and to be treated with respect for his/her personality, human dignity and privacy, without being discriminated against for social, economic, moral or ideological reasons.

Generally speaking, Spanish patients enjoy a series of rights that fall into eight major areas:

- Access to health care: patients have the right to obtain the health products and medicines necessary for their health, to be attended to within a period of time appropriate to the characteristics of their pathological process and in accordance with ethical and equity criteria, and to request a second medical opinion in the processes established by law.
- Patient autonomy: All patients have the right to receive all the information prior to any diagnostic or therapeutic procedure, to choose between the different existing therapeutic options and to renounce receiving the treatments or health actions proposed by health professionals if they consider it appropriate. Among the rights related to patient autonomy, current legislation also regulates the right to have patients' advance directives taken into account.
- Intimacy and confidentiality: patients have the right to be cared for in conditions that guarantee their privacy, dignity, autonomy and safety. On the other hand, they have the right to confidentiality of information related to their illness and to access personal data obtained in the care process. In this sense, patients also have the right to be asked for consent prior to the creation and dissemination of iconographic records and to the confidentiality of their genome information, as well as the security of not using this information for any type of discrimination.
- Experimentation and scientific research: it is recognized the right to know whether the prognostic, diagnostic and therapeutic procedures applied to the patient can be used for a teaching or research project, with the assurance that in no case will it pose an additional danger to their health. In the same way, it is recognized the patient's right to dispose of those biological samples coming from a biopsy or extraction is collected in order to obtain the opinion of a second professional or to continue his medical process in another

hospital if he/she so wishes.

- Disease prevention and health protection: This refers to the right to know the health problems of the community that pose a risk to personal or community health, as well as the right to have this information disseminated in understandable, truthful and appropriate terms. This includes the right to know the initiatives and benefits in terms of prevention and health protection, and the right to know the results of these initiatives and benefits.
- Care information and access to clinical documentation: Patients have the right to receive information about the benefits and services offered, as well as access to their clinical history, a complete document that will gather all the information about their state of health and the clinical and health actions carried out.
- Participation of patients and users: This includes the right to know and be able to identify, in any situation, the professionals who provide health care. Also, the right to provide complaints and suggestions and, on the other hand, the right to participate in health activities and the use of information technologies.
- Quality and safety of care: Patients have the right to humane and scientific-technical quality health care, as well as safe care, based on agreed and up-to-date clinical safety protocols.

iii) ***Legal regulatory framework in Spain***

The rights of patients are protected by a broad legal framework that begins with the Spanish Constitution itself. Specifically, article 43 of Spanish Constitution recognises the right to health protection, with the public powers being competent to organise and safeguard public health through preventive measures, as well as the benefits and services considered appropriate and necessary. The public authorities shall also promote health education, physical education and sport.

After the enactment of the Constitution and in relation to issues directly related to the rights of users of health services, a basic regulation was developed, contained in Law 14/1986, of 25 April, General Health, which recognizes the right to respect for the personality, dignity and privacy of the patient. It also includes the right to non-discrimination and to be informed about health services, as well as the right to confidentiality of all information related to their process. It also includes the right to be assigned a physician and to be notified whether the prognostic, diagnostic, and therapeutic procedures applied to him or her may be used for a teaching or research project.

The general principles established in the General Health Law were completed by Law 41/2002, of 14 November, which regulates the autonomy of the patient and the rights and obligations regarding clinical information and documentation. This law focuses its attention on the desire to humanize health services. Thus, it maintains maximum respect for the dignity of the person and individual freedom, on the one hand, and, on the other, it declares that the health organisation must guarantee health as an inalienable right of the population through the structure of the National Health System. 41/2002 reinforces the patient's right to autonomy. Specifically, it gives special treatment to the regulation of prior instructions that contemplate the patient's previously expressed wishes, as well as to everything related to the clinical documentation generated in the healthcare centres, hi-

ghlighting the rights of the users in this aspect.

After Law 41/2002 and after 16 years since the entry into force of the General Health Law, due to the profound changes in Spanish society, cultural, technological and socioeconomic as well as in the way of life, it was decided to adapt the health laws to the modernization of the environment. As a result, Law 16/2003, of 28 May, on the Cohesion and Quality of the National Health System, came into being. This law was created to establish a legal framework for all coordination and cooperation actions of public health administrations, guaranteeing equity, quality and social participation in the National Health System.

Law 16/2003 was modified by Royal Decree--Law 16/2012, of 20 April, on urgent measures to guarantee the sustainability of the National Health System and to improve the quality and safety of its services, according to which all those persons who hold the condition of insured, that is to say, those who are in one of the following cases, have the right to health care in Spain:

- To be an employed or self-employed person, affiliated to the Social Security and in a situation of registration or assimilated to registration.
- To be a pensioner in the Social Security system.
- To be a recipient of any other periodic Social Security benefit, including unemployment benefit and subsidy.
- To have completed the unemployment benefit or subsidy or other benefits of a similar nature, to be in a situation of unemployment, not to accredit the condition of insured under any other title and to reside in Spain.

IV. Social Protection

The National Health System manages the following health care services: public health services, primary care, specialized, emergency and pharmaceutical services. Among all these benefits or aids, we would like to point out in this chapter those which may be less known by the oncological patient but at the same time, it is important that those aids can be known by he/she since these patients surely have to use them.

In Spain, each Autonomous Community has transferred competences in the field of health. Therefore, the Health Ministries are the agencies in charge of carrying out and managing these benefits.

- Orthotic and prosthetic aid: For example: breast prostheses, wheelchairs, etc. It is an economic aid to cover the cost of the orthoprosthetic material and must be requested before the purchase. Information can be requested at the Patient Care Office of the referral hospital.
- Provision of sanitary transport: In order to support the access to National Health System, healthcare for patients who, due to clinical impossibility, or geographical distance from the health centre and previously justified, cannot access it. Patients can be accompanied when the age or clinical situation requires it. This service can be requested through the Patient Care Office of his/her health centre and/or through his/her reference doctor.
- Pharmaceutical benefit: it refers to the medications that are prescribed by the primary care doctor or specialist and are co-financed by the Social Security. The contribution (payment) for the medication

is made at the time of purchase and is proportional to the person income level of income, which is updated as a maximum, annually. It is essential to present the patient identification health card when acquiring the medication in the pharmacy, in order to establish the corresponding percentage.

In 2011, a measure was approved in Spain to support families in which there is a minor diagnosed with cancer or serious illness. It consists on an economic benefit and it compensates the reduction in income that these families have, considering that one of the two parents (they must both be active) reduces his/her working hours to his/her children.

V. Cancer and Labour Law Issues

Cancer patients have many doubts when they have to return and resume their professional activities, taking into account that there is not always a company policy sensitive to the needs of people with cancer in terms of adapting functions, schedules, permits, among other aspects.

In the case of having a recognized incapacity by the medical court, reflected in the corresponding incapacity certificate the cancer patient has four pathways to access work:

- Public Sector: public administrations (state, autonomous and local) have the obligation to reserve a minimum of 2-3%[11] posts of public employment calls for people with incapacities (these changes depending on each administration).
- Private company: companies with more than 50 workers have the obligation to cover at least 2% of their workforce[12] with people with incapacities. In addition, any company can obtain grants and reductions to hire people with incapacities.
- Self-employment: creating a company or business, for which there are also programs and grants that can help them.
- Special Employment Centre: companies in which at least 70%[13] of their workers are persons with incapacities and whose main objective is to carry out productive work by regularly participating in market operations and having as a purpose to ensure gainful employment.

Another different matter is, if the cancer patient receives an economic benefit. In this case, can the patient reconcile the fact of returning and resuming his/her professional activity with the payment of an economic benefit? When patients with cancer return to his/her professional activity they should take into account the following requirements:

- Temporary Incapacity[14]: the right to re-

[11] *Pursuant to* article 42 (paragraph 1) of the Legislative Royal Decree 1/2013, of November 29, 2013 approving the Revised General Law on rights of persons with incapacities and their social inclusion, published in the Official State Gazette on December 3, 2013 (available at: <https://www.boe.es/buscar/doc.php?id=BOE-A-2013-12632>), workers with incapacities must account for at least 2 percent of the employees of public or private enterprises employing 50 or more workers. This figure will be calculated on the total headcount of the enterprise concerned, regardless of the number of workplaces it has and of the types of employment contracts between the workers and the enterprise. Any workers with incapacities who are working at any given time at the public or private enterprises concerned under manpower supply contracts with temporary employment agencies will also be computed for these purposes

[12] See again the aforementioned precept of the Legislative Royal Decree 1/2013, of November 29, 2013 approving the Revised General Law on rights of persons with incapacities and their social inclusion.

[13] Information provided by the State Public Employment Service (SEPE), Spanish Ministry of Labor, Employment and Social Security. Available at: <https://www.sepe.es/contenidos/personas/encontrar_empleo/empleo_personas_discapacidad/centros_especiales_empleo.html>.

[14] The procedures and formalities related to Temporary Incapacity can be consulted on the Spanish Ministry of Labor, Employment and Social Security, available at: <http://www.seg-social.es/

ceive the benefit can be denied, cancelled or suspended by:
  - o Fraudulent action in order to obtain or maintain the benefits
  - o Working for another person or as self-employed worker
  - o Refusing or abandoning the prescribed treatment.
- Partial Permanent Incapacity[15]: the right to receive the subsidy is compatible both with the activity that the patient carried out before the illness and if he/she starts a new one.
- Total Permanent Incapacity[16]: The recognition of a total permanent incapacity implies the inability to perform the same work that was done, but does not limit to perform another type of work. For this reason:
  - o The right to receive the subsidy is compatible with carrying out a work as an employee or self-employee in the same company or in a different company.
  - o The right is incompatible with the performance of the same work.
- Absolute Permanent Incapacity[17]: the right to receive the subsidy is incompatible with the performance of any professional activity. However, in the event that the medical court has granted the cancer patient absolute permanent incapacity but the patient himself/herself considers that he/she can perform some kind of professional activity, he/she may request the review by the Medical Court (Incapacity Assessment Team).

VI. Cancer and Insurance Law

In terms of health insurance and cancer, some insurance companies include in their health insurance coverage and treatments, specifically, statements referring to cancer (known as oncological insurance).

The reasons that lead people to contract one of these policies are many, but there are some that stand out from others, such as the celerity and efficiency offered by private healthcare, as well as the preferential treatment, comfort or medical criteria.

But not only these advantages of private versus public healthcare make some Spaniards choose to have one of these products, but they are also attracted by the large number of coverage or services that may include. In this sense, there are already many insurance companies that pay special attention to cancer in their health insurance with specific guarantees: both preventive and medical coverage once the disease has been detected to the insured.

i) Insurance in the preventive phase of

Internet_6/Masinformacion/TramitesyGestiones/PrestaciondeIncapac44667/index.htm>.

[15] The procedures and formalities related to Partial Permanent Incapacity can be consulted on the Spanish Ministry of Labor, Employment and Social Security, available at: <http://www.seg-social.es/Internet_6/Trabajadores/PrestacionesPension10935/Incapacidadpermanen10960/RegimenGeneral/Prestaciones/Incapacidadpermanen35615/index.htm>.

[16] The procedures and formalities related to Total Permanent Incapacity can be consulted on the Spanish Ministry of Labor, Employment and Social Security, available at: <http://www.seg-social.es/Internet_6/Trabajadores/PrestacionesPension10935/Incapacidadpermanen10960/RegimenGeneral/Prestaciones/Incapacidadpermanen28700/BeneficiariosHechoc28703/index.htm>.

[17] The procedures and formalities related to Absolute Permanent Incapacity can be consulted on the Spanish Ministry of Labor, Employment and Social Security, available at: <http://www.seg-social.es/Internet_6/Trabajadores/PrestacionesPension10935/Incapacidadpermanen10960/RegimenGeneral/Prestaciones/Incapacidadpermanen28729/BeneficiariosHechoc28732/index.htm>.

cancer (before the disease)

Once a patient is diagnosed with cancer, it is important to adopt the appropriate treatment as well as follow-up visits and tests as a preventive measure. The aim of this test is the early diagnose of the disease in case of suffering it, and thus to start earlier with the appropriate treatment.

a) ***Prevention plans***

Health insurance can incorporate programs of preventive medicine for gynaecological cancer in women, prostate cancer or early diagnosis of breast cancer. They can also include the early diagnosis of colon cancer, although in this case, they can establish that the insured has a minimum age that is usually set at 50.

b) ***Tomosynthesis***

It is known as 3D mammography. It is a diagnostic test that allows to know with accuracy and precision the shape, size and location of a lesion suspected to be malignant. Among the advantages of tomosynthesis is the reduction of false positives and negatives. In addition, it eliminates, in many occasions, the need to carry out complementary studies since this technique avoids the superposition of images and detects very small lesions that in a conventional mammography would not be detected. Thus, it is possible to diagnose cancer in an initial state.

c) ***Second medical opinion***

One of the coverages that usually includes health insurance that covers this type of disease is a second medical opinion. Thus, they offer their policyholders diagnosed with cancer the coverage of a second medical opinion by oncologists of recognized prestige at an international level.

ii) During and after the cancer disease

a) Can*cer therapeutic targets*

In treatments against breast, gastric, lung, advanced colon or gastrointestinal stromal tumors, therapeutic targets allow to identify the type of tumor and the state of it before the beginning of the personalized oncological treatment. Nevertheless, the insurance company can specify what kind of therapeutic targets will cover and under what conditions.

b) ***Other treatments***

Another service that can offer medical insurance is the use of a Da Vinci robot for abdominal oncological surgery or blood diagnosis to determine oncological treatment. It is also possible to find PET scan (Positron Emission Tomography) for some diseases such as breast cancer, oesophagus, lung, pancreas or neck or head tumours.

c) Hair *prostheses*

There are treatments for the cure of cancer that have among their undesirable effects the loss of hair by the patient. Therefore, there are health insurances that include among their coverage for cancer one designed to provide the insured with hair prosthesis. Indeed, these elements contribute both to the psychological state of the patient and influence their recovery.

d) ***Psychological service***

In these cases, psychological care also becomes an essential element for many patients who need the help of professionals to face this difficult stage. The insurances can make available to their insured a psychology service whose specialists will be available 24 hours a day.

VII. Research and Cancer / Status and Legal Aspects of Biobanks in Spain

i) Informed consent form for biobank donors

Biobanks in Spain are devoted to the store and distribution of human biological samples for research in general terms. Biobanks are authorized by the National Public Administration.

In Spain, donors can give a broad consent for the storage and samples transfer from biobanks to research projects.

The need of prior consent is independent on whether the samples are intended for long-term storage or short-term use, or to be handled in an anonymous or coded way.

In the particular case of deceased persons, the gathering of samples is allowed to be done when the person had manifested his consent in life or at least there is no known expressed opposition to the use of the samples, according to the Biomedical Research Law 14/2007 and the Royal Decree 1716/2011. In this latter case, the family cannot object without a reasoned plea. In any case, efforts to gather information about the will of the deceased person should be made. The existence of advance directives will be explored and, in the absence of these, near family members of the deceased person and the attending health care workers will have to be consulted regarding the donor's will. That consultation will also have to be documented.

ii) Local data privacy law and principles

The data subject must give his/her written informed consent to the transfer and processing of his/her personal data abroad (European or not European countries) (Art 34.3 Royal Decree 1716/2001 and Art. 5.1 LOPD 15/1999 / Title VI. International data transfers. Article 40 et seq. Fundamental Law 3/2018 of 5 December on the Protection of Personal Data and Guarantee of Digital Rights).

He/she must be informed of its right to opposition concerning the personal data storage and processing and the right to access to the data for requesting their modifications, withdrawal or destruction.

The rights of the donors concerning their personal data refer to the information about the conditions of the processing, right to withdraw consent and right to access to the data. Health data, including genetic have to be stored within high security measures. Regarding the protection of data privacy and confidentiality in the context of Biobanks, Spain law is transposed from the specific EU directive. According to this, samples and the associated data that have been stored in Biobanks are to be transferred only in either an anonymous or a dissociated way. The Biobank is also responsible for ensuring that the transfer of the samples and data is done safely. The country or institution receiving the samples must meet the same safety requirements that exist in Spain.

iii) Specific ethical regulations/ workflow of Spain: human material transfer agreement between researchers and a biobank

The process for the transfer material between the Biobank and the researchers is regulated in Spain by the Royal Decree 1716/2011. The ethical evaluation of the project from an Ethics Committee is a criterion that the project has to fulfil to allow the Biobank to transfer the samples.

Biobanks can transfer samples only for specific research projects. Biobanks have ethical and scientific independent committees, that have to approve the transfer of the samples from the biobank to the researcher for the project.

A material transfer agreement (MTA) has to be signed for the transfer of the samples. The fair collection of the samples should be specified as well as the duties of each party. The ethical evaluation of the project in which the samples are going to be used would be attached.

The MTA to be signed between the investigator and the Biobank legal representative will include at least the following responsibilities according to the Royal Decree 1716/2011:

Duties of the recipient:

- Application of measures for the traceability of the samples.
- Availability of the donor's related genetic data obtained from the analysis of the sample or validated information related to donor's health.
- Undertakes to use the material in accordance with the effective legislation of the Provider's country.
- Use of the samples with the sole purpose of the specific project.
- Applications of security measures concerning data.
- Destruction or return of the sample after the research.

VIII. End of Life Issues

Actually, life perspective has been changed by medicine. Illnesses that in the past could be mortal, nowadays are treated by physicians with medicines or medical treatment. For this reason, elderly people have increased their life expectancy although they know that death is always at the end as a natural terminus of life. They always know how to live but they wanted to know how to die too as one of the most important and complicated decisions to be made in life. There are important situations where elderly people should take a decision about a medical treatment, for instance chemotherapy, or when they have consent to treatment but they wanted to forgo it. In both cases, one principle has emerged in medical practice: patient´s autonomy.

Although respect for the autonomous choices of persons runs as deep in common morality as any principle, autonomy's patient principle has been implemented in majority of legal orders since the middle of last century as the most important principle of clinical practice. As a consequence of this principle, one right is emerging: the right to self-determination, who is often expressed in terms of consent requirements for any kind of medical intervention, and every unauthorized touching of a person constitutes and damage which should be compensate under tort law or criminal law because it´s only the fact of consent which renders its lawful.

An enforcement of this principle and right is informed consent as a precondition of autonomous decision making and a requirement of a lawful medical treatment. Patients have the right to determinate what treatments they want or not to begin once they have informed by physicians of the most important information of the medical act, because right to self-determination is not only the right to decide it includes the right to choose among various types of treatments too when physicians full disclosure all proposed medical procedures, the material risks of those procedures and alternative courses of action. With the information, patients can accept the treatment and physicians can act,

but they may also refuse treatment. Patient´s autonomy consist not only to accept treatment, but also to refuse or forgo a treatment, even when this will result in death. In all these cases patients have the right to refuse treatment as a consequence of general principle of liberty of people.

In respect to refuse special attention should be play to one of the most important and significant principle — and interest — of our society, the sanctity of life, that can be enforce as an important limit to this right. A balance between society and patient's interest will be sought in each case and it will not be easy to decide.

Other important rights are affected or implicated by the decision of refusing or foregoing the treatment, especially when the decision is adopted based on personal or religious beliefs of patients. In this case, not only the principle of the liberty of the patient has to be considered, but also religious freedom, the right to privacy and the most important and fundamental right of the patients: the right to life.

In several cases, the decision of refusing or foregoing a treatment could conduct to the death of the patient. Cases where the patient is supported by artificial elements and solicited doctors to withdraw artificial nutrition or hydration are in deeply connection with one of the most controversial topics on health law and bioethics: euthanasia, that is forbidden by Spanish Criminal Code on article 143.3 and 4.

There is no doctrine about the differences between euthanasia and refuse to be treated that could help physicians or patients to make a clear and better decision, and this absence turn into a higher legal insecurity. In our opinion, this difference is very clear, and when patient's death is caused directly by the act or omission of the physician we are in a case of euthanasia that can be punished as accordance with Spanish Criminal Act. But if the case of a death is caused by natural factors of the illness although the act or omission of the physician, there is no euthanasia.

In the last years some Autonomies have passed specific Acts on Death with Dignity. This Acts has in common that they are inspired in the general principles of the Patient`s Autonomy Act. The main objective of this Acts on Death with Dignity is to enforce the autonomy of the person at the end of life and to give legal security to physicians in cases where there are doubts about patient´s acceptance to refuse or forego treatment and in the case of palliative sedation, an important right at the end of the life.

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WHITE BOOK ON CANCER PATIENTS' RIGHTS • FRANCE

Anne-Marie Duguet

(1)

I. Introduction

Protection of health is a constitutional principle enshrined in Article 11 of the preamble to the Constitution of 27 October 1946. The nation "guarantees to all … the protection of health … every human being who … is unable to work has the right to obtain adequate means of subsistence from the community".

In 1945, the social security system was created by Ordinances and based on the principle of national solidarity. Article L 111-1 of the Social Security Code states: "Social security is based on the principle of national solidarity. It ensures for all persons working or residing in France in a stable and regular way the coverage of maternity and paternity sickness expenses and family responsibilities … ".

Article L-111-2-1 further stipulates: "Protection against the risk and the consequences of illness is guaranteed to everyone regardless of age and health. Everyone contributes, depending on its resources, to the financing of this protection. The state which defines the objectives of the public health policy guarantees effective access of the insured to healthcare throughout the territory … ".

For many years, cancer has been regarded as a social scourge and patients have special care and benefits for drug reimbursement, care and hospitalization, and, depending on the circumstances, in respect of invalidity, compensation for the loss of work capacity etc.

Public and private actions to fight cancer have been initiated by the League against Cancer (private body), and at the state level, a specific policy for the fight against cancer has been in place since 2003 within the framework of the Cancer Plans.

II. Rights for all Patients

The Act of 4 March 2002 on the rights of the patients and the quality of the health system devotes a chapter to "informing users of the health system and expressing their will". This legislation is general in scope and applies to all patients.

The Public Health Code in articles L 1111-7 *et seq.* and R. 1111-1 *et seq.* contains the main references concerning patients' rights: right of direct access to the medical file, right of refusal or interruption of treatment, appointment of a trusted person, drafting of advance directives to make known the care at the end of life etc.

These rights are explained in the "Hospitalized Patients' Charter"[2]. A summary of this charter is given to the person with the welcome booklet on the day of the hospitalization.

The general principles of the Charter are as follows:

- Anyone is free to choose the health facility that will take charge of it, within the limits of the possibilities of each establishment. The public hospital service is accessible to all, especially the poor and, in case of emergency, to people without social security coverage. It is suitable for people with disabilities.
- Health facilities guarantee the quality of reception, treatment and care. They are attentive to the relief of pain and do their utmost to ensure a dignified life for all, with special attention to the end of life.
- The information given to the patient must be accessible and fair. The hospitalized person participates in the therapeutic choices that concern them. He or she can be assisted by a trusted person freely chosen.
- A medical procedure can only be performed with the free and informed consent of the patient. He or she has the right to refuse any treatment. Any adult can express his wishes for his end of life in advance directives.
- Specific consent is provided, in particular, for persons participating in biomedical research, for the donation and use of the elements and products of the human body and for screenings.
- A person who is invited to participate in biomedical research is informed, in particular, about expected benefits and foreseeable risks. His or her agreement is given in writing. His or her refusal will not affect the quality of care he or she will receive.
- The hospitalized person may, except in accordance with exceptions of the law, leave the establishment at any time after having been informed of the possible risks to which he or she may be exposed.
- The hospitalized person is treated with respect. His or her beliefs are respected. Its privacy is preserved as well as its tranquillity.
- The respect of the private life is guaranteed to any person as well as the confidentiality of the personal, administrative, medical and social information related to him or her.
- The hospitalized person (or his legal representatives) has direct access to his health information. In the event of death, his or her beneficiaries benefit from this same right, under certain conditions.
- The hospitalized person can complain on the care and hospitality she has received. In each establishment, a committee on relations with users and quality of care ensures, in particular, the respect of the rights of users. Everyone has the right to be heard by a person in charge of the establishment in order to express his or her grievances and to seek reparation for any damage that they consider they have suffering, in the context of a private agreement procedure and / or before courts.

[2] See annex to the circular DHOS/e1/DGS/SD1B/SD1C/SD4A/2006/90, of March 2 2006.

i) *Subjective rights for all patients*

a) *Right to private life, confidentiality and professional secrecy*

The right to private life (privacy) is protected by the French law by Article 9 of the Civil Code: 'Everyone has the right to respect for his private life.' Private life is a subjective human right that must be respected by all. Criminal sanctions are provided for violation of someone's private life (Article 226-1) that applies to all citizens. Courts now compensate for consequences of such violation. The jurisprudence of civil courts has defined private life as covering everything related to the person, his family, his home and his health. Only the individual himself or their beneficiaries may authorize the disclosure of his private life.

Breach of privacy is achieved by the interference of third parties in the private sphere without permission of the subject. This interference is sanctioned by civil courts for any damage and disturbance and the courts can stop the infringement by the seizure of books or of newspapers. There is a special disciplinary sanction for the doctor in accordance with Article 51 of the Code of Medical Ethics "the doctor shall not interfere without any professional reason in the family affairs or in the privacy of patients".

Confidentiality is the respect for the confidential nature of an information by the person who is depository when this information is either given directly by the person himself or herself or when any other person who is led to know it, through the documents to which he or she could access (correspondence, records, reports).

The obligation of confidentiality is imposed on all professionals who are thereby led to know the elements of privacy and all information relating to the person and his or her family. The obligation of confidentiality is associated with the civil servants status.

More broadly, all secret information brought to the attention of professionals is protected, and the disclosure is punished under the Penal Code by section 226-13: 'The disclosure of a secret information by a person who is the possessor/depository either by his status or his profession or due to a function or to a temporary assignment is punished with imprisonment of one year and a fine of € 15,000.'

Concerning doctors and health professionals the various codes of conduct/deontology or rules for professionals recall their duties to respect professional secrecy in accordance with the law. Thus, professionals who disclose secret information expose themselves to both penal and disciplinary sanctions.

Professional secrecy

The professional secrecy is the basis of the trust between patient and physician. The respect of the secrecy is protected by the Penal code, the deontological code and the law on patient rights.

In the penal code, the violation of professional secrecy is a punishable offence since the first publication of Penal Code. The original Article 378 of the Penal Code was addressed to doctors, surgeons, and any person holding confidences that he or she received during his or her practice. The obligation to respect the professional secrecy is of public policy, which means that every citizen must be sure to confide to any professional doctor, lawyer, solicitor or priest, without being afraid that their secrets could be revealed.

The deontological basis of the professional secrecy: Article 4 (Article R 4127-4 CSP) states the

obligation to respect professional secrecy « …established in the interest of patients applies to any doctor in the terms established by law. The secret covers everything came to the knowledge of the physician in the practise of his profession, that is to say not only what has been entrusted to him, but what he saw, heard or understood. »

Moreover, medical ethics requires compliance by the secret to people attending physicians: "The physician must ensure that the people who assist him in the exercise should be educated about their obligations of professional secrecy and comply. (R 4127-72)

It should ensure that no harm is carried by his entourage to secrecy that attaches to his professional correspondence and ensures the protection of medical documents and correspondence (Article R 4127-73 CSP).

The Law of 4 March 2002 the Article 1110-4

In this Article, the legislator takes up the main ethical obligations of professional secrecy and its applications in the performance of activities of care and protection by the health professionals and institutions. It enshrines the right to respect private life and confidentiality of information concerning any person that a professional or an institution takes into care.

The secret's content covers all information about the person who came to the knowledge of health professionals and all staff member. It applies to all health professionals and all professionals involved in the health system. Unless the person explicitly refuses it, the transmission of information among professionals is possible to ensure continuity of care or to ensure the best healthcare services. When a person's care is covered by a team of health professionals in a health facility, the information about this person are deemed to be given by the patient to the entire team.

Safeguards to protect the confidentiality of data are organized in accordance with the recommendations of the *Commission Nationale Informatique et Libertés* (CNIL)[3]. A new offence is punishable: obtaining or attempting to obtain copies of this information in violation of this section is punishable with imprisonment of one year and EUR 15,000 fine.

Towards third parties, medical confidentiality does not preclude the family, relatives of the sick person or the person of trust defined in Article L 1111-6 receive the necessary information to enable them to provide direct support to it, unless opposed him.

Finally, professional secrecy does not prevent information about a deceased person from being delivered to its rightful owners, unless a contrary intention by the person before his death has been notified.

b) *Right to information on care delivery, cost of care and access to medical files*

Information on care delivery

Art L1111-2 CSP provides that "everyone has the right to be informed about his state of health." The information relates to investigations, treatments or preventive actions, their usefulness, urgency, consequences, frequent or serious risks normally foreseeable as well as therapeutic alternatives. The information also relates to the consequences in case of refusal of care.

The professional is not obliged to inform in case of emergency or impossibility.

The will of the person who wishes to be left in ignorance of a diagnosis or a prognosis must be respected unless third parties are exposed to a risk of contamination.

[3] For more information about the National Commission for Data Protection, see: <www.cnil.fr>.

The information is given in the framework of an individual interview.

According to the jurisprudence, the information must be fair, clear and appropriate to obtain free and informed consent. The information is personalized and adapted to the interlocutor in order to be understood. Minors have the right to receive information adapted to their degree of maturity, or to the degree of discernment of adults under guardianship.

Information on the cost of care

Information on the costs and coverage of care by health insurance, is provided by Articles L 1113-3 to L1111-3-6 CSP.

In healthcare facilities, a clear public announcement indicates that the fees charged correspond to the services actually delivered. Professionals practicing a liberal activity in public establishments must inform their patients of the cost medical care in accordance with the regulatory obligations of the liberal practitioners.

At the end of the hospitalization, the patient receives information on the cost of all the services delivered, indicating the part covered by the health insurance, the part covered by his complementary insurance and the part that remains at the charge of the insured. (art L 1111-3-1 of the CSP).

For liberal practitioners if the act exceeds 70 euros, a preliminary estimate must be provided.

Article L 1111-3-2 requests that the information concerning the conditions of taking charge of and the possible waiving of the advance of costs, as well as the display of rates, be posted in the patient's reception areas. Conventional practitioners of sector 1 are obliged to apply the reimbursement rates of health insurance, however, in sector 2, the fees are free, but must be established with tact and measure.

All health professionals practicing on a liberal basis are required to post their tariffs (decree of May 28, 2018).

Access to the medical files — Art L1111-7 CSP

Since the law of 4 March 2002, the patient has direct access to his hospital file. He or she must make a written request. He or she will get an answer within 8 days and can consult after a reflection period of 48 hours. Hospitals have a specialized service for accessing medical records.

This consultation can be done directly by the subject himself or herself in the hospital or through a doctor appointed by the patient. This may be the case in a serious condition such as cancerous conditions so that the patient is not alone in reading a serious diagnosis or prognosis. The person may also request that copies of the record be sent to him or her at his or her expense.

After death, the legal successors of a deceased person can access the medical record unless the subject himself has objected to during his lifetime.

For minors or incompetent adults, the holder of parental authority or the legal representative exercises this right. A doctor or a person can be mandated by the patient (express written mandate). The information contained in the file is confidential, so family, entourage, employer, insurance, bank do not have direct access, but the patient to which the information is directly communicated can transmit it to whomever he or she wants.

The accessible documents are: examination results, prescriptions, surveillance sheets, X-rays, correspondence between health professionals, transmission texts between professionals, the nursing file, etc. Is excluded from communication the information obtained is excluded from the third parties who do not participate in the care of the

patient and the personal notes of professionals that are not intended to be exchanged[4]).

c) ***Consent to care***

Consent to care is organized by the Art L1111-4 and L1111-5 CSP.

Article 16-3 of the Civil Code provides: "The integrity of the human body can be impaired only in cases of medical necessity for the person or exceptionally in the therapeutic interest of others. The consent of the person concerned must be obtained beforehand except in the event that his/her condition necessitates a therapeutic intervention to which he or she is not in a position to consent ".

Article L 1111-4 of the CSP, introduced by the law of March 4, 2002 states "Every person takes, with the health professional and taking into account the information and the recommendations that he or she gives him or her the decisions concerning his or her health. The article specifies that no act may be performed without consent, and that consent may be withdrawn at any time.

Consent is free, informed and delivered orally. However, for some acts the attention of the subject is drawn to the important nature of the consent and in these circumstances a written consent is collected. (genetic diagnostic (article L 1131-1-1 CSP and R 1311-4 CSP); prenatal diagnostic examination (art L2131, L2131-4 and L 2131-4-1 CSP; acts of medical assistance to procreation (art L2141-2 CSP), contraceptive sterilization (art L 21-23-1 and -2 CSP), termination of pregnancy (art L 22-12-15 CSP), participation in research involving the human person (L 1122- 1 CSP).

The refusal of care of the patient must be respected, however if this decision of refusal endangers the life of the subject, the doctor must do everything to convince him or her to accept the necessary care. If the patient confirms his decision after a " reasonable period of time ", the doctor must respect and accompany him or her in this decision.

The information prior to the expression of the consent of the minors must be adapted to the capacities of understanding of the minor and his or her assent must be sought. In biomedical research, the formal opposition of the minor cannot be ignored.

d) ***The person of trust (Art L.1111-6 CSP)***

Every person of the age of majority can designate in writing "a trusted person". This person receives information from the healthcare professionals when the patient is not able to be informed or to express his / her will. This designation is not mandatory, but highly recommended. The choice of the person of trust is free, he or she is not paid. At each hospitalization the patient is asked about the name of the trusted person.

This person can be a loved one, a family member, or anyone who has the patient's trust. Its designation is revocable at any time.

The duration of the designation is free, revocable or replaceable at any time. The person should be informed of the patient's wishes for the decisions to be made when the subject will no longer be able to express them.

The designation is done by a document written and signed by the user himself or herself and co-signed by the person of trust[5].

The person of trust and his or her contact de-

[4] See "*Recommandations de bonnes pratiques relatives à l'accès aux informations*".

[5] A form has been proposed by the HAS. Available at: <https://has-sante.fr/portail/upload/docs/ application / pdf / 2016-03 / da_personne_confiance_v9.pdf>.

tails are mentioned in the medical file.

Outside the decisions concerning treatment choices and choices, this person is consulted in specific situations: in clinical trials conducted in an emergency situation (art L1122'2 CSP), for genetic tests the person of trust must be consulted when it is impossible to obtain consent (art L1131-1CSP).

Finally, the testimony of the person of trust is collected at the end of life when the subject is unable to express his or her will and that advance directives have not been drafted (law of 2 February 2016).

The advice of the trusted person prevails on that of the family or the relatives.

e) ***Pain management (Art. L1110-5 to L1110-5-3 CSP)***

"Everyone has the right to receive care to relieve their suffering. Pain must be in all circumstances prevented, taken into account, evaluated and treated ". The term suffering covers both physical and mental pain.

Specialized structures for the management of chronic pain have been set up for patients' examinations and in hospital centres for pain.

In hospitals, there are mobile pain management teams that can move to other facilities: inter-hospital and home-based networks as part of city-hospital networks.

Special provisions have been made for pain at the end of life in the event of refractory suffering allowing a deep and continuous sedation to be put in place until death.

f) ***Advanced directives***[6]

Anyone may make known in writing his or her end-of-life wishes regarding the conditions of prosecution, limitation, termination or refusal of treatment or medical procedures. (Art R. 1111-17 CSP).

The adults under guardianship can also draft advance directives with the authorization of the guardianship judge or family council, the tutor can neither assist nor represent him in this task.

Advanced directives allow the doctor to know the wishes of the patient for his or her end-of-life, i.e. when the person is suffering from a serious and incurable condition in advanced or terminal phase. The person may plan to stop or limit curative or palliative treatments, but these guidelines are now binding on the physician (since the law of 2016) except when they endanger life, a committee[7] will decide about the application.

Directives[8] may be written on plain paper or in a form prescribed by law[9].

The person indicates: 1) his or her surname, first name, date and place of birth, 2) his or her wishes regarding his end of life related to the conditions of prosecution, limitation, termination or refusal of treatment or medical procedures. The person himself or herself determines the content. If he or she is in perfect health, the instructions will be of a rather general order.

[6] Articles of the Public Health Code: Art. L1111-11 and L1111-12, from Art. R1111-17 until R1111-20 and R.4127-37-1

[7] See Art. R4127-37-2 of the Public Health Code.

[8] See the documents of the *Haute Autorité de Santé sur les Directives Anticipées*, available at: <http://www.has-sante.fr/portail/jcms/c_2619437/fr/les-directives-anticipees-concernant-les-situations-de-fin-de-vie>.

[9] See <https://www.legifrance.gouv.fr/jo_pdf.do?id=JORFTEXT000032967746>.

Otherwise, if the person has a serious illness, the guidelines may be more specific depending on the pathology and its treatments. For example, the person may ask not to or no longer receive artificial nutrition and hydration if this is the main act of keeping alive. 3) he or she dates and signs.

If the person able to express his / her will cannot write, two witnesses are solicited whose trusted person if it has been designated; the witnesses add their names and attach their attestation to the advance directive.

Advance directives can be filed and kept in the medical file of the family doctor, in the hospital file, by the patient at home, by the person of trust, or by a relative.

Advance directives can be revoked or changed at any time. They are valid indefinitely.

ii) ***Sanitary democracy***

Health democracy associates users of the health system with the development and implementation of health policies. This approach is enshrined in the law of 4 March 2002 on the rights of the patients and the quality of the health system, and developed by the law of 21 July 2009 on the reform of the hospital relating to patients, health and territories. Strengthening health democracy is one of the main thrusts of the National Health Strategy.

a. ***Patient representatives in hospital***

Users are associated with the organization of the health system since the law of 4 March 2002. This is a new relationship between caregivers and patients who gives the floor to users of the health service. The health scandals of tainted blood, nosocomial infections have led patients' associations to organize themselves and have their rights recognized collectively. As early as 1996, an ordinance provided for the participation of user representatives on the boards of directors of the institutions. A commission of relationship with the users and the quality of the support is created.

To represent the users, the associations of patients must have an approval which is granted according to the missions of the associations by a commission of the ministry of health. Several successive laws came to reinforce the representation of the users. The number of mandates is between 12000 and 15000. They are present in the hospital authorities: committee for control of nosocomial infection, the hospital supervisory board, and other bodies such as the protection committee for protection of persons involved in research (which gives an opinion on the research protocols) and the commission for conciliation and compensation.

In healthcare establishments, the name of the user representative is mentioned in the welcome booklet, the representatives of the users participate in the drafting of an annual report and contribute in particular to the information of the patients.

b. ***Users' Committee (Articles L 1112-3 and R 1112-94 of the CSP)***

The law of modernization of the health system of January 26, 2016 creates user commissions in public and private institutions. It is composed of five people: two mediators (one doctor and the other not doctor), two representatives of users and the legal representative (or a person he designates) who chairs the commission.

The mediator doctor is competent to know the complaints related to the medical activity, the mediator non-doctor is competent for all the others. The user is heard by the mediators within 8 days after his or her complaint.

The commission is notified of the minutes of this meeting. After having heard the complainant, the commission makes recommendations when it considers it useful, which are transmitted to the complainant within 8 days after the meeting.

The commission ensures the respect of the rights of the users: it has access to the complaints and with the agreement of the person or its beneficiaries, the commission can obtain the medical data relating to these complaints, and the answers given by the establishment.

The commission examines complaints that are not associated with a grievance, indemnity or jurisdictional appeal. It informs the user of the rights of recourse and conciliation which are offered to him or her.

The commission is associated with the organization of the care pathway and of the policy of safety and quality of care. It is informed of the actions taken in case of serious adverse events. The commission writes an annual report with the analysis of her activity and the relevant proposals which is transmitted to the health security agency.

c. *Patient associations (Articles L 1114-1 and R 1114-6 to R 1114-17 CSP)*

The law of 4 March 2002 provides that patient associations wishing to represent the interests of users receive approval for this mission. As of 31 December 2017, there were 157 associations accredited at the national level and 300 at the regional level for a total number of 11.500 seats in the different instances.

The authorization, given for 3 years, is subordinated to an effective activity for the protection of the rights of the people. The activity is defined in art R1114-1 of the CSP: 1- promotion of the rights of sick people and users of the health system to the public authorities and within the health system; 2- participation of patients and users in the development of health policies, 3- prevention, help and support for patients and users.

Association members receive training which entitles them to receive compensation.

Accreditation is issued by a National Accreditation Committee of the Ministry of Health. The commission receives the annual activity reports of the associations. Accreditation can be withdrawn if, according to its report, the association does not fulfill its missions.

iii) *Organization of end-of-life care*

The legislator successively organized palliative and end-of-life care. The need for legislation is linked to the fact that doctors have an obligation to provide the necessary care and, even if the patient objects, to continue the care. In 1999, the Palliative Care Act allowed the patient to refuse traditional care and choose palliative care and defined the framework for their implementation.

The law of 22 April 2005 on the rights of the patient at the end of life clarified the conditions under which it is now possible to interrupt treatment without really addressing the issue of euthanasia, applied to very limited situations.

a. *Palliative care law*

The Act of 9 June 1999 has been incorporated into the preliminary chapter of the Public Health Code (in French CSP) and recognizes access to palliative care as a right of the sick person (Art.L.1 A of the CSP). It defines palliative care as: "active and ongoing care provided by an interdisciplinary team in an institution or at home. They are designed to relieve pain, to alleviate psychological suffe-

ring, to safeguard the dignity of the sick person and to support those around him or her " (Art L. 1 B.). Moreover, the sick person can refuse any investigation or treatment"(Art L. 1st C.).

A policy is defined for the implementation of the device in the sanitary organization scheme in healthcare establishments through palliative care units or in the framework of alternative structures to hospitalization by creating mobile teams and organization for hospitalization at the home of the patient. Volunteers trained in end-of-life support assist the healthcare teams with the patient's agreement for the comfort of the patient and the support of his entourage.

The associations that organize the intervention of the volunteers have a charter that defines the principles they must respect in their action. These principles include respect for the philosophical and religious opinions of the accompanied person, respect for his / her dignity and privacy, discretion, confidentiality, and freedom from interference in care. When volunteers intervene in health care facilities, a convention organizes their activity.

The law then provides for provisions concerning the patient's entourage by creating an accompanying leave to assist a person at the end of life, amending the Labour code.

An employee whose ascendant, descendant or a person sharing his or her residence is the subject of palliative care is entitled to receive an accompanying leave for an end-of-life person. This leave has a maximum duration of three months and no salary is paid. It ends either at the end of this period or within three days of the death of the person being accompanied.

b. End of life laws

The law of 4 March 2002 permits refusal of care in all circumstances to avoid unreasonable obstinacy. The advance directives have supplemented these provisions.

2005 Law on Patients' Rights and End-of-Life

The 2005 Law on Patients' Rights and End-of--Life aims to limit unreasonable obstinacy in care. Article L. 1110-5 of the CSP, a paragraph is inserted as follows: These acts must not be pursued by unreasonable obstinacy. When they appear unnecessary, disproportionate or having no other effect than the mere artificial maintenance of life, they may be suspended or not undertaken. In this case, the physician safeguards the dignity of the dying person and ensures the quality of his life by providing the care referred to in Article L. 1110-10" (Palliative care).

To avoid the legitimate fear of patients having their lives, Article L. 1110-5 of the Public Health Code provides: "If the physician finds that he cannot alleviate the pain of a person suffering from a serious or incurable condition in the advanced or terminal stage, by applying treatment which may have the secondary effect of shortening his life, he must inform the patient, without prejudice to the provisions of the fourth paragraph of Article L. 1111-2, the trusted person referred to in Article L. 1111-6, the family or, failing that, one of the relatives. The procedure followed shall be recorded in the medical file ".

The opinion of the trustee person, except in the case of emergency or impossibility, prevails over any other non-medical advice, excluding advanced directives, in the decisions of investigation, intervention or treatment taken by the doctor.

Through this law the patient can decide alone when he or she is in advanced or terminal stage of a serious and incurable condition. He or she can

limit or stop any treatment the doctor respects his will after having informed him/her of the consequences of this choice. The decision of the patient is recorded in his medical file.

Any person of full age who is not terminally ill may also, by advance directives, make known his or her will. These advance directives indicate the end-of-life wishes of the person regarding the conditions of limitation or cessation of treatment. They are revocable at any time. Provided that they have been drawn up less than three years before the person's unconsciousness, the doctor shall take it into account for any decision to investigate, intervene or treat the person.

A collegiate procedure is provided for by the code of medical ethics to limit or stop treatment when the terminally ill person is unable to express his / her will. The doctor may decide to limit or discontinue treatment that is unnecessary, disproportionate or has no other purpose than the artificial prolongation of the life of that person. The collegial procedure shall be implemented after consultation with the trusted person or the family or, failing that, a relative and, where appropriate, the advance directives of the person.

Law No. 2016-87 of 2 February 2016 creating new patient rights at the end-of-life

It complements existing legislation and introduces two new therapeutic provisions: "deep and continuous sedation" and "relief of suffering".

Deep sedation and continuous sedation (Art L. 1110-5-2) cause an alteration of consciousness which is maintained until death, associated with analgesia and the cessation of all maintenance life treatments. It is put in place at the request of the patient with a serious and incurable condition and whose vital prognosis is committed in the short term and which presents a suffering refractory to the analgesic treatments. When the patient cannot express his / her wishes if the physician stops a life--sustaining treatment, in accordance with the law, the latter can apply a deep and continuous sedation associated with analgesia according to a collegiate procedure.

Deep and continuous sedation can be performed at home or in a health facility.

Relief of suffering (Article L. 1110-5-3): Everyone has the right to receive treatment and care to alleviate his or her suffering, even if it may have the effect of shortening life. In this case, the physician must inform the patient. Suffering must in all circumstances be prevented, taken into account, evaluated and treated, even at home.

III. *Rights of Patients with Cancer*

1. *General principles and health policies*

a. *Centres for the fight against cancer (CLCC)*

Since 1945, cancer centres have been set up, which are private non-profit institutions for the fight against cancer (CLCC). They perform a public service mission providing care for research and teaching. The CLCCs provide integrated care: prevention, early diagnosis, treatment and post-therapeutic follow-up.

They are spread over 20 sites and present in 16 regions. The UNICANCER group values their organization model, pooling their resources.

b. *The "cancéropôles"*

Established in 2003, they implement the national research support policy at regional and interregional level. They combine hospital-university services, research organizations and, for certain

research projects, industrialists. The objective is to animate and coordinate the teams in the same geographical area by promoting the pooling of different research disciplines involving clinicians, biologists, epidemiologists, public health experts, etc. There are 7 "*cancéropôles*" labeled covering the entire territory or France.

c. ***The INCA National cancer Institute (2004)***

In the first part of the Public Health Code, which deals with the general protection of health, concerning the fight against cancer, article L 1415-2, created by Act No. 2004-806 of 9 August 2004, defines the missions of the National Cancer Institute in charge of coordinating the fight against cancer:

- Observation and evaluation of the cancer control system;
- Definition of benchmarks of good practices and management in oncology;
- Information to professionals and the general public on all the problems related to cancer;
- Participation in the setting up and validation of continuing medical and paramedical training for professions;
- Implementation, financing, coordination of specific research and development actions;
- Development and follow-up of joint actions between public and private operators in cancerology in the fields of prevention, epidemiology, screening, research, teaching, care and evaluation;
- Participation in the development of European and international actions;
- Carrying out, at the request of the ministers concerned, any expertise on issues relating to cancerology and the fight against cancer.

The National Cancer Institute draws up an annual activity report which is transmitted to the Government and the Parliament.

Report No. 10, published on July 4, 2018, states that as of January 1, 1997, 886 establishments were authorized. Outpatient surgery is favoured with 36 projects funded for 2 years.

Research: 163 million euros are allocated to research including 93 million by institutional bodies. CNIB has strengthened the multidisciplinary nature of research projects.

For the development of personalized medicine, INCA supports access to innovation and targeted therapies by: supporting the implementation of NGS (Next-generation Sequencing diagnostic targets) in molecular genetics platforms and in diagnostic laboratories on oncogenetics.

d. ***Cancer plans***

The Cancer Plans organize a national and global cancer control strategy, an integrated approach that covers the field of research, prevention, organization of care and post-cancer care.

Cancer plan 2003

The fight against cancer was structured in France in 2003 around national plans, aimed at mobilizing public health actors around prevention, screening, care, research and support for the patient and his or her relatives.

Launched on March 24, 2003 by the President of the Republic, the 2003-2007 Cancer Plan has triggered a decisive momentum in the fight against cancer in France and in the care of patients.

The Plan has helped reduce tobacco consumption through a comprehensive tobacco control

strategy that includes price increases, a ban on sales to people under 16, information campaigns and targeted actions. to young people and women and the development of cessation aids.

Organized screening for breast cancer was generalized in 2004 while organized screening for colorectal cancer was tested from 2002 to 2007 in 23 pilot areas.

The quality criteria defining the minimum standard of quality in care have been established, as health facilities must meet these criteria to be authorized to treat patients suffering from cancer (in surgery, radiotherapy and chemotherapy).

A new dynamic has been launched in cancer research and 7 "*cancéropôles*" have been set up to facilitate research in the regions.

By setting up the National Cancer Institute in 2005, the State has set up a health and scientific agency to coordinate the fight against cancer.

The 2009-2013 Cancer Plan

It was structured around five major axes (Research, Observation, Prevention and screening, Care, living during and after cancer), 30 measures and 118 actions. Three cross-cutting themes were aimed at: 1) better addressing health inequalities to ensure greater equity and efficiency in all cancer control measures; 2) stimulate the analysis and consideration of individual and environmental factors to personalize care before, during and after illness; 3) strengthen the role of the family doctor at all times of the care to allow a better life during and after the illness.

The Plan worked to strengthen the quality and safety of care throughout the country. Organizations have been adapted for the care of children with cancer, elderly patients and people with rare cancers. Access to personalized medicine and participation in clinical trials have also increased. The Plan supports therapeutic innovations, and advances research, including cancer genomics.

The organized screening program for colorectal cancer has been extended to the entire territory.

In order to ensure a continuity of the patient's journey, the personalized care and post-cancer programs were tested as well as the coordination between hospital teams and city workers, in particular the treating physicians (family doctors).

The third plan 2014-2019

wishes to give the same opportunities to everyone everywhere in France. The government has allocated 1.5 billion euros. It aims to cure more sick people, preserve continuity and quality of life, invest in prevention and research, optimize management and organizations.

In order to cure more patients, the emphasis is on earlier diagnoses, support for technological and therapeutic developments, accelerating innovation for the benefit of patients, broad access to individualized diagnosis (personalized medicine or precision medicine).

For the quality of life the plan advocates personalized care and reducing the impact of cancer on personal life, improving access to insurance and credit, and better knowing the patient experience during and after cancer. Prevention and research are valued with a reduction of risks, better nutrition and regular physical exercise, as well as the fight against excess alcohol and tobacco. For the optimization of the piloting, the plan aims to make live the health democracy with the representatives of the patients and to adapt the modes of financing to the challenges of oncology.

i) ***Organization of care for patients with cancer***

The diagnosis of cancer opens patient a specific journey to the patient. The diagnostic announcement system proposed by the 2003-2007 Cancer Plan, provides a time for discussion and explanation of the disease and treatments.

It begins with a medical time: announcement of the diagnosis and proposal of a treatment with Personalized Program of care.

The caregiving time allows patients and their relatives to be listened to supplement medical information and to identify psychological difficulties.

A time of support offers social support and care support: social worker, psychologist, physiotherapist…

A time of articulation with the city medicine to optimize the good coordination between healthcare establishment and attending physician.

a. Access to care

Social benefits fully supported by the social security

The management of cancer patients is organized under the long-term illness insurance scheme (ALD). This scheme was founded in 1945 and reformed by the law n ° 2004-810 relative to the health insurance, has for objective to offer to the chronically ill a particular follow up in order to facilitate their access to the care. This system applies to diseases whose chronicity requires prolonged treatment and particularly expensive treatment. The Social Security Code provides in article L 160-14,3 ° and 4 ° for the management of medical care. 100% (without making any money advance) and extended daily allowances, up to 3 years.

Cancer disease is on the list of long-term conditions for "malignant tumours, and malignancies of the lymphatic or hematopoietic tissues."

Coverage includes acts performed during hospitalization, consultation with health professionals in the city, health products and care-related transportation.

The ALD is noted by the attending physician according to the criteria of Article D 160-4 of the Social Security Code. The doctor completes a care protocol defining the pathology, the care coordination tool, the list of practitioners in charge of patient follow-up. The protocol is sent to the medical control of the social security which gives its opinion to the administration of the social security. The manager of the social security notifies the insured person of the decision and a duplicate certificate stating the ALD is sent to the doctor who gives a copy to the patient.

b. Hospitalization (treatment in health care facilities)

The specific cancer care activity is defined in article R6123-86 to 89 of the CSP. Created by the decree n ° 2007-388 of March 21st, 2007 art 1). It aims to treat solid malignant tumours and haematological malignancies.

It takes authorization to treat cancers. It is granted by the Regional Health Agency (ARS) to public or private institutions for: cancer surgery, radiotherapy, the use of radioelements, chemotherapy and other medical treatments specific to cancer.

The conditions for granting the authorization to distribute care to cancer patients are as follows:

- Being a member of a coordination or network of cancer care, which allows to ensure for each patient a multidisciplinary consultation to organize the announce-

ment of the diagnosis the establishment of a personalized therapeutic program in accordance with the referential of care and follow up defined by the INCA and referring to the recommendations of scientific societies.

- Organizing access to care and necessary support throughout the illness, including pain management, access to palliative care, psychological support and increased access to social services.

In addition, the establishment in connection with other structures, even abroad, provides access to innovative treatments and clinical trials.

To ensure the best possible care, authorization is granted only if the establishment complies with minimum annual activity thresholds.

Special provisions in emergency: when a patient is operated urgently for a malignant tumour in a facility that does not have an authorization, the institution refers the patient to an authorized institution (Article R 6123-91 CSP).

For other care than surgery, such as radiotherapy, authorization is given according to the technical platform available to the institution.

For institutions participating in the territorial network of oncology who participate in the care of people (for chemotherapy, follow-up care, rehabilitation and palliative care) the authorization is not necessary if the care is prescribed by a professional practicing in a registered establishment. (art R 6123-94 CSP).

c. Home care

Doctors and health professionals (nurses, kinesitherapists, etc.) can go to patients' homes to provide care. It is an outpatient care organized according to the needs and type of patients.

Nursing home care services (SSIAD) intervene at home when patients cannot move. Their interventions are covered by the Social Security Insurance. They are done on medical prescription. They facilitate the maintenance at home of the chronic diseases of elderly and disabled people.

If other social benefits are needed, such as home helpers, the multi-purpose home care and support services provide both nursing home care services and other home assistance services (housekeeper, preparation of meals etc.)

The liberal nurses provide various services. They can be grouped together in nursing health centers and intervene on medical or hospital prescription. Nurses can travel to the home or provide care at the Nursing Center. Nursing health centers are considered as proximity structures of first resort.

Home-based hospitalization (HAD) is a form of hospitalization that allows, at home, certain technical care, intensive or complex that the liberal sector, even coordinated, cannot take care of. It guarantees continuity of care (7 days a week, 24 hours a day) in a familiar environment.

HAD intervenes exclusively on medical prescription and with the agreement of the attending physician (family doctor or general practitioner) who ensures medical care throughout the stay. It is reimbursed by the Social Security.

Palliative care can be provided by an interdisciplinary team in an institution or at home. They aim to relieve pain, soothe mental suffering, safeguard the dignity of the sick person and support those around him. End-of-life individuals who wish to stay at home can receive home palliative care.

d. Social security coverage for patients with cancer

The social security insurance covers the cost of health care and health care products (benefits in care) and the loss of wages due to illness (cash benefits).

Drugs and care

Social security insurance covers benefits for medical care and health products. For routine illnesses, these benefits are reimbursed leaving the insured person to pay a "user fee" that varies according to the type of benefit or product (20%, 30%, 40%). The user fee can be covered by a private insurance.

For serious conditions requiring long-term care such as cancer, the patient has special conditions for long-term care ("*affection de longue durée*": ALD long term disease).

ALD support is given for a disease whose care and follow-up is carried out over an extended period of more than 6 months. There is a list of 30 diseases including cancer, established by the Ministry of Health. These diseases are covered 100% by the health insurance (no user fee) but with a flat-rate participation of the insured "the remaining dependent". The attending physician defines a protocol of care.

There is a follow-up post-ALD (recommendation of the High Authority of Health) which covers 100% the medical or biological procedures necessary for the follow-up of the ALD for which the patient was 100% supported when he or she benefited of the ALD (except transport and health products for therapeutic use).

ii) *Specific policy for children*

Childhood cancer is a rare disease that accounts for 1 to 2% of all cancers Each year, about 2,500 new cases of cancer are identified in children and adolescents.

Among the 17 objectives of the 2014-2019 cancer plan, the Plan also pays particular attention to the needs of children, adolescents with cancer, to advance access to innovation and further improve the quality of care, as well as the accompanying children and their families during and after illness.

a. ***New treatments***

Identifying new treatment targets requires further progress in understanding the mechanisms of tumour formation and development

The 2014-2019 Cancer Plan provides for a scaling up of the genome sequencing on molecular genetics platforms, for patients with relapsed or refractory disease firstly targeted and then extended (exome, whole genome), to reach 60 000 patients benefiting from sequencing in 2019.

As part of the ICGC international consortium, France is committed to funding the complete genome sequencing of two paediatric tumours, retinoblastoma and Ewing's sarcoma.

b. ***Access to medicines***

Children with particularly complex cancer, or who are in a situation of therapeutic failure, must be directed quickly to clinical trials that allow them to access innovative medicines.

The interregional oncopaediatric recourse organizations (IROs), which guarantee the quality of the care taken across the territory, are particularly responsible for facilitating and encouraging the inclusion of children in ongoing clinical trials, provided in the Cancer Plan so that accommodation and transportation costs are covered by the sponsor of paediatrics clinical trials to promote their access.

c. ***Reduction of side effects and sequelae***

Since 2014, a paediatric oncology intergroup has been formed. Its objectives are: the development and conduct of therapeutic trials to optimize the treatment, acceleration and increase of inclusion of children and adolescents in clinical trials, participation in personalized medicine projects organized by the Institute: the development and submission of translational research projects to the Institute's calls for projects; mobilize paediatric oncology researchers in multidisciplinary programs, such as the Integrated Program for Cancer Research (PAIR) dedicated to paediatric cancers

The objective of the "*PAIR Pédiatrie*" is to: improve current approaches (chemotherapy, radiotherapy, surgery, etc.); to encourage new therapeutic approaches (targeted therapies and immunotherapy, cryotherapy, imaging methods …) and to optimize long term longitudinal follow — up of cured paediatric patients.

In parallel, the Institute is studying the long-term future of people who have been diagnosed with cancer in childhood, including through specific cohort studies and data provided by the Cancer Registry.

iii) ***Research and cancer***

a. Institutions

Research in France is coordinated by the Ministry of Higher Education and Research and the Ministry of Health. The main organizations are:

- The INSERM, the French National Institute for Health and Medical Research, founded in 1964, is the only research organization dedicated exclusively to human health. Of the 318 units that compose the INSERM, 37 of them are dedicated to cancer research for a budget of 70 million euros.
- The CNRS National Center for Scientific Research devotes a budget of 60 million euros to cancer research in 53 research units.
- The CEA, the Atomic Energy and Alternative Energies Commission, supports research into health technologies: radiology, diagnostics and imaging.
- The INRIA, the National Institute for Research in Computer Science and Automation, is researching imaging tools.
- The Pasteur Institute works on cancers of infectious origin (liver, cervix) and on vaccines.
- The INCA defines cancer research programming and dedicates 50 million Euros to research in the form of calls for projects. Approximately 170 projects are funded each year after evaluation by a committee of experts.
- The AVIESAN and the ITMO cancer in 2007 the research structures were reorganized in the form of Alliances. The Alliance for Life and Health Sciences AVIESAN is divided into 10 thematic Institutes Multi-Organisms ITMO, one of which is devoted to cancer. Its mission is to coordinate the research strategies defined by the INCA.

b. ***Cancer registries***

A registry is a structure that performs "a continuous and exhaustive collection of nominative data relevant to one or more health events in a geographically defined population, for research and public

health purposes, by a team with appropriate expertise". The cancer registries are now an indispensable tool for the surveillance of cancers but also for the observation and evaluation of treatments.

The first French registers were created from 1975 on individual initiatives with a dual objective of surveillance and research. In 1986, the creation of the National Register Committee (CNR) enabled the registers to be included in a national public health and research policy.

Cancer registries can be general cancer registries or specialized cancer registries:

- General cancer registries collect information on all cancer sites. The Cancer Plan (2003-2007) provided for the creation of new registers to increase the population covered by registers and the representation of urban populations as well as to improve the geographical representativeness of the national estimates provided by the registers.
- Special populations registries and Specialized cancer registries collect information on specific localizations (digestive tract, haematological malignancies, breast, cervix, central nervous system, thyroid) or on particular populations (children).

In 2009, metropolitan France has a network of 25 registers, qualified by the CNR:

- 12 metropolitan general registers covering 14 departments spread over the entire territory and currently cover around 20% of the population (*Bas-Rhin, Calvados, Doubs and Territoire de Belfort, Gironde, Haut-Rhin, Hérault, Isère, Loire-Atlantique, Manche, Somme, Tarn, Vendée*) as well as the register of Lille and its area of proximity. These metropolitan registers are supplemented by two general overseas registers (Martinique and Guyana and Guadeloupe.
- 8 registers specialized in certain "organs" (digestive in *Côte-d'Or* and in *Saône et Loire*, in *Calvados* and *Finistère* — haematological in *Côte-d'Or, Gironde and Basse-Normandie* — breast and gynaecological cancers in *Côte d'Or* — central nervous system in *Gironde*);
- The multicentric register with national vocation of pleural mesothelioma — *Mesonat*.
- Two national child registries covering all cancers occurring between 0 and 14 years of age included: National Register of Childhood Hematological Diseases (RNHE), which has national data since 1990 and National Register of Solid Child Tumors (RNTSE).

In 2014 the CNR was replaced by the Registration Evaluation Committee (REC) set up by Public Health France. The committee carries out an independent expertise by experts of registers and themes treated by registers. It assesses the interest of the register, its functioning, its exhaustiveness, the adequacy between the means envisaged or implemented and the purposes presented, and its work undertaken in the field of research.

As of November 30, 2016, 31 cancer registries have been evaluated by the Registry Evaluation Committee (REC), 28 of which include the financial and scientific partnership "Cancer Registries Francim, Hospices Civils de Lyon (HCL), National Cancer Institute (INCa) and Public Health France ".

c. Medical research

This is the presentation of the general framework of medical research. Nevertheless, along this presentation the particularities of research on

patients with cancer are enlightened.

Since 1988, the French law establishes a legal framework and organized safeguards to protect people participating in the research. The 'biomedical research is organized and performed on human beings for the development of biological and medical knowledge' (Article L 1121-1 CSP). The Article L1121-2 provides three cumulative conditions: biomedical research is based on the latest state of scientific knowledge and on an adequate preclinical testing. The foreseeable risk incurred is out of proportion to the expected benefit to these people or the interest of this research; finally, research extends the scientific knowledge of the human being and means that will improve his condition.

In addition, biomedical research must be designed to minimize pain, discomfort, fear and any other foreseeable disadvantages related to a disease or research. The interest of people who are involved in biomedical research always prevails over the interests of science and society.

A new law entered in force in November 2016 defining three categories of according to the risks: (1) interventional research that involves an intervention on the person not justified by its usual treatment. They include drug trials in accordance with the European Regulation of 16 April 2014 on clinical trials and other research using health products or not; (2) minimal risks interventional research, excluding research on drugs, which involves only minimal constraints, (3) non-interventional research that does not involve any risk or constraint and in which all acts and products are used in the usual treatment.

The legal framework

The research is conducted by an 'investigator' who directs and supervises the conduct of the research; he is a medical doctor with the appropriate skills and experience. The promoter is a physical person or an entity (laboratory, institute, any research organization) taking the initiative of the research and ensuring its management and finance.

The promoter must submit a research project to a Committee of Protection of person (CPP) to get an opinion (on the terms and conditions of validity of the research with regard to the relevance of the research, the risk-benefit balance, the procedures for informing and obtaining consent). The approval of the CPP is necessary to begin the research, as well as the authorization given by the French Agency for the Safety of Medicine and Health Products (ANSM).

Increased Protection for vulnerable People: Pregnant women, new mothers, breastfeeding women (Article L 1121-5), persons deprived of their liberty, hospitalized psychiatric patients, persons admitted to a health or social facility (Article 1121-6 of the Public Health Code public), minors (Article L 1121-7 of the Code of Public Health), the adults being subject of a measure of legal protection (guardianship and curatorship) or unable to consent (Article L 1128-8 of the Code of Public Health), may be allowed to participate in biomedical research only under the following conditions: either the expected profit is to justify the incurred foreseeable risk, or — research is warranted in view of the expected benefit to other women in the same situation or to their children or other persons within the same legal or administrative status or other minor and provided that research of comparable effectiveness cannot be carried out on another group of population. In this case, the predictable risks and burdens of research should be minimal.

Relationship with the subject that lends itself to research

The physician investigator defines the conditions of recruitment of persons and the criteria for inclusion are assessed by the CPP, as well as the exclusion criteria that can challenge any person for whom participation in the research would be detrimental.

The Information and Consent (Articles 1122-1 and 1122-1-2 Code of Public Health)

The Information: People of legal age (18) or emancipated receive from the investigator an information allowing them to give a free and informed consent.

For interventional research, the information is given orally and presented in a written document that states: (1) the purpose, methodology, and duration of the research; (2) expected benefits, constraints and foreseeable risks, including when the research is stopped before its term; (3) possible medical alternatives; (4) the terms of medical care that are at the end of research, if such support is necessary, in case of a premature termination of the research, and in case of an exclusion of the research; and (5) the opinion of the protection of persons committee (CPP) and the authorization of the ANSM. The investigator shall also inform the subject of the research of his right to receive, during or after the research any relevant information about his health; (6) The investigator informs the person of his right to refuse to participate in research or to withdraw his consent at any time without any consequences in terms of personal liability.

Exceptionally, where in the interest of a sick person the diagnosis of his illness has not been revealed to him, the investigator may keep secret some information with the agreement of the CPP. This is the case for cancer when the subject does not know his or her diagnosis.

At the end of every kind of research, the person may be informed of its overall results. The means of information is defined in the information sheet.

The Consent

The law makes a distinction for the consent according to the kind of research (Article L1122-1-1 CSP).

For interventional research the free and informed consent is given in writing or, if not possible, certified by a third party. For minimal risks interventional research, the informed consent may be oral or in writing. For non-interventional research the consent is presumed. This means that the subject is informed of the research and of his or her right of opposition. Without an expressed refusal, the non-interventional research is performed.

Regarding secondary use of data, the promoter may ask the subject, at the time of consent, to agree to have his or her data used for further research for scientific purposes only. The person may withdraw his or her consent to such further use or exercise his power of opposition at any time. (Article L1122-1-2)

The Information and Consent of Incapable Subjects

Non-emancipated minors receive information adapted to their ability to understand. Minors are consulted if their condition allows to seek their personal commitment. Their refusal or revocation cannot be refused. Permission to participate in research is given by the holders of the exercise of parental authority, i.e., by both parents. However, if any of the missing parent cannot give his permission within the time required for the methodological requirements, authorization may be given by the parent who is present if this research presents

only negligible risks and constraints and has no influence on the medical care of the minor and when the research is performed during medical care.

Protected adults (guardianship) or incapable of expressing their consent and not subject to a measure of legal protection receive an information adapted to their ability to understand. They are consulted if their condition allows it to seek their personal commitment. Their refusal or revocation can never be ignored.

When adults unable to express their will are not subject to a measure of legal protection, permission is given by the person of trust or family, or by any person closely associated with the person concerned. However, if the CPP considers that the research involves a serious risk of breach to the privacy or integrity of the human body, authorization is given by the judge supervising the guardianship.

d. Biobanks for tumours

There are two types of tumour banks ("*tumorothèqyues*"):

- Health-related tumour banks whose aim is to preserve biological samples as part of the dossier, which allows to return to these biological archives in order to specify a diagnosis or a therapeutic orientation. Cryopreservation is a prerequisite for performing molecular examinations that improve the diagnosis and therapeutic management of patients. This activity is included in the authorization of health facilities for the treatment of cancer.
- Tumour banks for research are research projects in the framework of the law.

Legal framework of biobanking for research purposes

The Law 2004-800 (August 6, 2004) defines the biologic samples collections as: "the pooling for research purposes of biologic material from a group of subjects selected according to the clinical or biological characteristics of one or several members of the group, as well as the derivate products" (Art. L 1243-3 of Public Health Code).

As a basic principle, in the French law, the human body is protected by the Civil Code. A person is not allowed to sell products or parts of his or her body (article 16-1 of the Civil Code). The person has only the right to authorize their use for care or research.

Rights of the patients on the conservation of biological samples stored in collections for research

The Law 94-654 on the donation and use of components and products of the human body provides the conditions for removal of tissues or organs for treatment and research on the subject alive and after death.

Storage for a research protocol: Storage of biologic samples collected for research purposes is organized by the code of public health. A free and informed written consent is required by the article L. 1122-1 of the Public Health Code.

Specific regulations are set up for genetics since 1996: a decree regulates the collection of biological samples established for genetic purposes. Moreover, the analysis of genetic characteristics is protected by the Civil Code which requires an express and written consent (article 16-10 of the Civil Code) : "The examination of the genetic characteristics of a person is allowed for the purpose of medical of scientific aims . The explicit consent

of the person is required before the examination after the information of the person on its nature and its finality. The consent form mentions the finality of the examination and may be revoked at any times".

Many samples are collected for clinical purposes and might be interesting for research as well (secondary use) The article L.1243-3 of Public Health Code: allows the secondary use of material collected during the medical care, for biomedical researches.

The subject implicitly consents to the use of biological material from his body for medical diagnosis and treatment, but must be informed of the use for another purpose. so that he or she possibly could exercise her or his right of opposition to the research use and storage (article L.1211-2 of the Public Health Code).

The opposition to secondary use is defined in the Article L1211-2 of the Public Health Code: "the use of elements and products of human body for a medical or scientific purpose different from the original purpose, may be possible when there is no refusal expressed by the subject well informed of this different utilisation".

Rights of patients in the trade and transfer of samples of their biological material to third parties in France and abroad.

The Directive 2004/23/EC: exchanges of tissues and cells organizes standards of quality and safety for exchanges and sales of human tissues and cells. Although elements of the human body are out of trade, the free movement of goods within the European Union is possible in order to facilitate the exchange of samples and data between clinicians.

Biobanks created for research purpose

A biobank is a research protocol under the supervision of a medical doctor. A positive opinion of the CPP (Research ethics committee) is necessary to start the collection as well as a declaration to (or in some cases an authorization of) the Ministry of research.

The subject must be informed of the aims of the biobank, the duration of the biobank, the name of the person in charge of the biobank and the agreement for biobanking. An express and written informed consent is required.

The collection of data with the samples must comply with the regulations of data protection (declaration to the CNIL and respect of the provisions of the GDPR).

In foresee of secondary use for the same purpose, the information must clearly tell the secondary use in the same purpose, otherwise a new consent will be requested.

Exchanges in another laboratory and outside the EU countries need an authorization by the Ministry of research, and the consent of the subject for exchanges outside of EU countries

An express consent is necessary or data collection regarding ethnic origin, or genetic characteristics.

There is an exception when it is impossible to ask the person for a consent to research: the CPP can allow not to get new consents.

Sanctions for biobanking without consent or without the compulsory authorizations in the Penal code.

iv) Cancer and work

Workers with cancer have rights to work and must not be discriminated. In addition, patients whose condition has stabilized, wish to go back to professional activity. A set of provisions are provid-

ed to facilitate their reintegration into work.

Work can lead to cancer because of exposure to the carcinogenic risk of certain products found in the environment of work. French legislation provides for compensation for workers with work-related diseases, including cancers.

a. Rights of patients living with cancer at work

Non-discrimination

The employer has no right to dismiss or refuse the hiring of an employee because of his state of health: the principle of non-discrimination. Article L1132-2 of the Labour Code provides that "no person may be disqualified from recruitment or access to a training period or period of education in a factory, no employee may be punished, dismissed or be the object of a direct or indirect discriminatory measure because of his state of health or disability". The probationary period allows the employer to assess the employee's qualifications and to assess whether the positions held are compatible. During this period, the contract of employment can be broken by both parties without obligation to justify the reasons.

In labour law, disease and sickness do not constitute grounds for dismissal. However, repeated absences or prolonged illnesses that disrupt the company's progress may constitute a real and serious cause of dismissal.

The subject with severe illness has leave authorizations to follow the medical treatment necessary for his condition.

A work interruption will be prescribed for the duration of the treatment. The delay is limited, but the recognition of a long-term ALD condition makes it possible to prolong the interruption of work beyond 6 months. For civil servants the family doctor may prescribe a work interruption of up to 12 months which can be transformed and long-term leave for up to 5 years.

Working with cancer

To enable gradual rehabilitation at work, a therapeutic half-time can be granted. It must be prescribed by the family doctor in agreement with the medical service of the medical insurance which fixes the daily allowances and the duration.

Unfitness for work declared by the occupational physician may lead to dismissal.

If the person is not able to return to work under the same conditions as before his pathology, there are different ways of adapting working conditions after cancer treatment: 1) a part-time recovery, 2) a retraining after training for a less arduous position, 3) if 66% of the work capacity is lost due to illness before the age of 60, the person stops work and receives a disability pension, 4) early retirement when the subject is over 60.

Working after cancer

More than 3 million people in France live with cancer or are cured. The VICAN5 survey of 4174 people explored patients aged 18 to 82 years with the 12 most common cancer sites diagnosed 5 years before.

Professional life and financial situation are permanently modified. 26% of people have seen their income drop. The people most affected are those who have lost their job since the diagnosis, those who were in the performance business or were self-employed, and those with significant sequelae.

20% of 18 — 54 years olds who were employed at the time of diagnosis no longer work 5 years later. This loss of employment affects the most vulnerable

in the workplace, the least educated, the least experience and precarious contracts. For those working at the time of diagnosis, 54% have kept the same job, 17.4 have changed. 5.9 are unemployed, 75% are disabled and 13% are retired.

Therapeutic part-time was used by 24% of employees. This benefit was implemented on average 17 months after diagnosis and more frequently in women.

Adaptation of working time is the most common measure in improving working conditions after cancer.62,7% of the people who worked at the time of the diagnosis benefited from it and are mostly satisfied. More women than men, more people in stable contracts or in the public sector.

b. Cancers linked to work (occupational cancers)

The Labour Code provides specific rules for the use in the workplace of certain carcinogenic products. Enhanced medical surveillance is planned according to the workstations and the risks of exposure. European Regulation 1207/2006 of 12 December 2006 (REACH) defines the restrictions on the manufacture, use and placing on the market of carcinogenic products.

Exposure limits

The Labour Code defines the occupational exposure limit values that are binding (benzene, wood dust, vinyl chloride, etc.).

Considering the chemical hazard for example the articles R.4412-1 to R 4412-57 organize the prevention the limit values of exposure (art R.4412-149 and -50) are checked in the companies at least once a year (R 4412-27). The carcinogenic and mutagenic toxic risk for reproduction is also taken into account; Work involving benzene is prohibited for pregnant or lactating women (art D 4152-9), work exposing cancer-causing chemicals is prohibited to young workers under 18 years of age (D. 4153-17 and -18). Enhanced medical surveillance is planned every 24 months for employees exposed to carcinogenic chemical agents (articles R. 4624-18 and -19).

Among the occupational cancers detected, asbestos causes the largest number of deaths. Many cancerogenic substrates are known to cause occupational cancers. For the lung cancer are involved asbestos, arsenic, bischloromethylether, cadmium, certain compounds of chromium, tar and coal soot, roasting of nickel, fumes of iron oxide, silica. Aromatic amines and tars cause bladder cancer. Sinuses are reached by, some chromium compounds, nickel mesh, wood dust. Skin cancers are caused by mineral oils, coal tar pitches, arsenic, ionizing radiation. Brain tumours are caused by exposure to nitrosoguanidines and nitrosoureas. Finally, malignant blood diseases and leukaemias are caused by exposure to benzene, ionizing radiation. Finally, vinyl chloride causes liver cancer.

Recognition and compensation of occupational cancers

The Social Security Code defines as an occupational disease and therefore as a professional cancer, any cancer being "the direct consequence of the exposure of a worker to a physical, chemical or biological risk", or resulting "from the conditions in which he exercises his professional activity" (Article L. 461-1). The conditions concerned by the recognition of an occupational disease are included in the occupational disease tables of the general scheme of social security system and of the agricultural system.

A cancer can be recognized as professional and compensable if it appears in one of the tables of

occupational diseases of the Code of Social Security. They set the criteria for recognition. These tables include: the designation of the disease and / or symptoms; the delay of taking charge; the work likely to cause the affection in question.

There are about twenty professional cancer tables for the general social security system and for the agricultural system. If there is no table or if the criteria of the tables are not met, there is a complementary system since 1993. In this case a Regional Committee for the recognition of occupational diseases is seized which can recognize the professional nature of the cancer.

The declaration of a professional cancer is made with an initial medical certificate, which describes very precisely the nature and symptoms of the cancer and the probable consequences.

If the Social security insurance recognizes the professional nature of the cancer, the care is organized within the framework of the risk of *"accident at work / occupational disease (AT / MP)"*. Namely: 100% coverage of medical care, hospital package and transportation.

In the event of a work leave for occupational cancer, daily allowances are paid from the first day of sick leave, amounting to 60% of the gross salary for the first 28 days, then 80% from the twenty-ninth day. If there are sequels, an annuity or compensation is granted based on the disability rate.

In the event of exposure to asbestos during the professional activity, a specific benefit is provided for the early cessation allowance for asbestos workers (ACAATA). ACAATA allows them to cease their activity, sometimes as early as age 50, and to receive an allowance until the date on which the right to a full pension is opened.

Asbestos victims are compensated under a special fund (FIVA) if they have developed mesothelioma or other attacks related to occupational or environmental exposure to asbestos.

v) *Cancer and life insurance*

Access to bank loans requires insurance. The risks of occupational incapacity or death related to cancer constitute obstacles to the purchase of insurance for a loan which becomes more expensive because of the aggravated risks and patients are regularly denied the necessary loans to the purchase of their house, even if they have recovered from their cancer.

The AERAS agreement, "Secure and Borrow with an Aggravated Health Risk", entered into force in 2007 with the objective of expanding access to insurance and borrowing.

A commitment of the 3rd cancer plan resulted in the signature on 2 September 2015 of an amendment to the AERAS agreement between the Ministry of Finance, the Ministry of Health, the federations of banking and insurance, private insurances and associations of patients and consumers, which establishes a "right to be forgotten". It takes into account major therapeutic advances.

It is the non-declaration of a cancer occurring prior to the application for the loan in the following two cases:

- A borrower whose cancer has been diagnosed before and until the age of 15 years and whose treatments have been completed for 5 years.
- A borrower whose therapeutic protocol (surgery, radiotherapy or chemotherapy) has been completed for more than 15 years, irrespective of the cancer he or she was suffering from.

A reference grid is established for pathologies that do not present an excess risk without having to wait for the 10-year period (a list made public for the first time on 4 February 2016 and updated in March 2017).

For those who do not fulfil the conditions of the right to forget, the AERAS agreement provides for consumer loans and for real estate and professional loans.

In the event of disputes relating to the agreement, the mediation committee of the AERAS Convention may be seized.

The contracts concerned are those of the AERAS agreement for insurance applications relating to loan transactions of up to € 320,000, the duration of which is such that the age of the borrower does not exceed 70 years at the end of the loan.

COMPARATIVE CONCLUSIONS

PORTUGAL • SPAIN • FRANCE

Subjective rights

In Portugal, Spain and France there is no specific legal regulation to condense the rights of cancer patients. Nevertheless, the general patient rights legislation is applicable. Every and each one of these countries have a "patients' law", applicable to patients in general. In specific situations, for example in labour law, France has a more protective regime for cancer patients, specifically introducing the right to gradual rehabilitation at work after cancer. In Portugal, on labour law and tax benefits, a comparison between the cancer patient and the person with impairment or disability is accepted.

Beyond the specific rights of cancer patients, the following general rights should be highlighted on the three legal systems: the right of choice, informed consent, adequate healthcare provision, confidentiality and personal data protection, and the right to be accompanied and to receive visits.

Through advance directives, the patient may designate a health care proxy for the moment when he/she can no longer express his/her will. However, in France there is the special figure of "person of trust", with no exact parallel in Portugal and Spain.

In Portugal, ill children are represented by their parents; in case of major medical proceedings both the authorization of the father and the mother are required, even if parents are not married, separated or divorced. The adolescent after 16 years old can, in general, give the sole consent for medical treatments.

In Spain, the legal age to consent is 16, but if the child is under 18 and his/her life is endangered, the treatment is dangerous or has important consequences for his or her health, it is also necessary the consent of his/her parents or persons who have the authority on the minor. If the minor is under 16, authorization both from the father and the mother is required.

In France, the legal age to consent is 18, but under 18 the child gets relevant information, and his or her assent is necessary. If the adolescent refuses a treatment or a research protocol, his or her refusal is respected, except when his or her life is endangered.

End-of-life decisions

The right to refuse treatment is assured in all the referred legal systems and there is a strong focus on relieving pain and discomfort. Patients have the right to palliative care, which is one of the most important issues in the health policies of the three countries analysed in this book.

In France and Portugal, deep and continuous sedation is regulated and applicable to patien-

ts with a serious and incurable condition, whose vital prognosis is committed in a short term. In Spain, some Autonomies have passed specific Acts on Death with Dignity, with the objective of enforcing the autonomy of the person at the end of life and giving legal security to physicians in cases where there are doubts about patient´s acceptance to refuse or forego treatment and in the case of palliative sedation.

In Portugal, persons in the context of advanced disease and end-of-life are entitled to refuse, under the law, artificial support of vital functions and even to refuse hydration and feeding on the last days of life.

Dysthanasia, euthanasia and assisted suicide are not allowed on the three legal systems considered.

Pain treatment

Portugal, Spain and France have several laws concerning the development, implementation and financing of medicines to combat cancer pain. In Portugal, patients with cancer are exempt from medical fees and the medicines for pain purchased outside the hospital could be 90% financed by the State. In France and Spain, cancer treatments are 100% covered by Health Insurance.

Associations of patients with cancer

On the three countries, associations of cancer patients provide a major contribution to the development of dialogue platforms and manifestos written by and for patients, although also directed to the society in general, focused on prevention, treatment, life with cancer and technical support to caregivers. This kind of associations play a key role on these systems because they provide social, legal and psychological support to patients and their families, thus contributing to sanitary democracy. At the same time, it is common for patient associations to provide training and workshops to health professionals and social workers.

In Portugal and Spain, the participation of representatives of patient associations in the management board of hospitals is not required, unlike in France, where they are involved in hospitals' governance.

Specific policy for children

In South-Western Europe, we don't see a coherent line of policies and social responses to children with cancer. Portugal, Spain and France assure fertility preservation and provide different kind of subventions for children and adolescents with cancer, although the participation on ongoing clinical trials are facilitated.

In Portugal, there is a special school program for long term treatment in pediatric hospital, and cancer patients can have access to scholarships and a special contingent of access to higher education, benefiting from an arrangement to missed classes. On the other hand, labour law provides a special regime of absences and dispensation to assist child with cancer.

In Spain, parents can leave their work to stay in hospital or at home with the child, but they don't receive compensation for it. At hospital, minors receive education and NGO's have special programs to provide them with a better stay during the hospitalization period.

In France, one of the parents can leave work to stay in hospital or at home with the child; compensation is given by the social security.

Healthcare systems

The three countries have distinctive characteristics, however, all of them are based on a universal

system that is essentially free. The most particular system is the Spanish, due to the fact that it is fragmented between different autonomous regions.

The Portuguese Constitution was approved and proclaimed the citizens' right to health care by "the creation of a universal, free-of-charge National Health System". In 1979, Basic Health Law regulated the NHS as being a universal and general health system, free at the point of use, i.e, "a universal, comprehensive and free-of charge National Health Service". The Portuguese health system is characterized by three co-existing and overlapping systems: the universal NHS; special health insurance schemes for particular professions or sectors (e.g. civil servants, employees at banks and insurance companies), called the health subsystems; and private voluntary health insurance. In Portugal, the majority of patients are treated in the National Health Service, even when they benefit from alternative health protection systems such as ADSE (public service workers) or SAMS (bank workers) as well as health insurance contracts available from different insurers. These alternative medical insurances can set limits to the medical care provided and when patients reach this limit, treatments continue in the National Health Services. The healthcare delivery system in Portugal consists of a network of public, social and private healthcare providers.

The Spanish National Health System is the agglomeration of public health services that has existed in Spain since it was established through and structured by the General Health Law of 1986. Management of these services has been progressively transferred to the distinct autonomous communities of Spain that today are assumed by all the autonomous communities that have development their own health services. The Spanish National Health System is the agglomeration of the autonomous health services and the state national service. All citizens have access to the country's universal healthcare system. It covers most healthcare free of charge. Foreigners also have the right to access NHS services if they're working in Spain or if they're over the retirement age. Undocumented immigrants have the right to treatment if they enter an emergency room or they are minors or women on pregnancy. Protection of health is a constitutional principle enshrined in Article 11 of the preamble to the Constitution of 27 October 1946. The nation "guarantees to all … the protection of health … every human being who … is unable to work has the right to obtain adequate means of subsistence from the community"

In France, in the year of 1945, the social security system was created by Ordinances and based on the principle of national solidarity. Article L 111-1 of the Social Security Code states: "Social security is based on the principle of national solidarity. It ensures for all persons working or residing in France in a stable and regular way the coverage of maternity and paternity sickness expenses and family responsibilities … ". Article L 111-2-1 further stipulates: "Protection against the risk and the consequences of illness is guaranteed to everyone regardless of age and health. Everyone contributes, depending on its resources, to the financing of this protection. The state which defines the objectives of the public health policy guarantees effective access of the insured to healthcare throughout the territory … ".

Research and Cancer / Personal Data

Relevant legislation on clinical research exists in all three countries as well as various opinions from national and local ethics committees. We find some standardization of legislation in the 3 coun-

tries on issues such as protection of personal data and biobanks since it is based on European legislation. As far as research is concerned, there is a very relevant aspect of the French legal system: whereas in Portugal and Spain health data collected for healthcare purposes can only be used for this purpose, and a new consent of the data subjects must be obtained in case of using these data for research purposes, in the French case data collected for care purposes can be used for research as far as the subject does not express his or her opposition (art L 1211-2 CSP) . Spain and Portugal joined the Declaration on linking genomic health data across borders, while France did not join.

Cancer at Work – Cancer and Insurance

Regarding labour law, the three countries have rules of non-discrimination based on illness and protection of the worker's confidentiality; there is still a minimum set of rules for the protection of these patients. However, the most advanced regime is the French one because it provides for the possibility of gradual rehabilitation at work after cancer (half time working) and disability pension when the person loses 66% of his/her working capacity (e.g.).

With regard to insurance, once again we find a standardization in the three countries with regard to non-discrimination. In Portugal, there is an exemption from life insurance when contracting house loans; in France, there is the agreement AERAS: 'secure and borrow with an aggravated health risk' (2 September 2015).

SUBJECTIVE RIGHTS :
PATIENT INFORMATION AND CONSENT ANNOUNCEMENT OF THE DIAGNOSIS
(CANCER PLAN)

Portugal	Spain	France
- Subjective rights are protected by several laws but the most relevant is the general patient rights legislation (*e.g.* Law 15/2014 of March 21, art 156 and 157 Penal Code). - Diagnostic is part of the duty of information. - National Programme for Oncological Diseases (PNDO) – 2017-2020.	- Subjective rights are protected by several laws but the most relevant is the Law 41/2002, of 14 November, which regulates the autonomy of the patient and the rights and obligations regarding clinical information and documentation. Also, the rights of patients are protected by the Spanish Constitution (article 43). - 1st Cancer Plan in Spain (2003-2018) as a result of the collaboration between the Ministry of Health, the scientific societies, the patients, professionals, experts and representatives of the different sectors, autonomous communities (also at a regional level: e.g. Basque Country Oncology Plan 2018-2023). 2nd Cancer Plan in Spain (in progress).	- Subjective rights are protected by the law of 4 March 2002 on patient rights: private life; confidentiality and professional secrecy; information on care and on the cost of care, consent to care (no care without consent (some except ions) access to medical file, appointment of a person of trust. - Special policy for announcement of diagnosis organized by cancer plan 2003-2007: medical time for discussion and explanation of disease and treatment; proposal of treatment with a personalized program of care; social support and care support; articulation with the city medicine.

ASSOCIATIONS OF PATIENTS WITH CANCER:
ROLE OF ASSOCIATIONS AND THEIR RELATION WITH DOCTORS

Portugal	Spain	France
- Subjective rights are protected by the law of 4 March 2002 on patient rights: private life; confidentiality and professional secrecy; information on care and on the cost of care, consent to care (no care without consent (some except ions) access to medical file, appointment of a person of trust.	- Subjective rights are protected by the law of 4 March 2002 on patient rights: private life; confidentiality and professional secrecy; information on care and on the cost of care, consent to care (no care without consent (some except ions) access to medical file, appointment of a person of trust.	- Subjective rights are protected by the law of 4 March 2002 on patient rights: private life; confidentiality and professional secrecy; information on care and on the cost of care, consent to care (no care without consent (some except ions) access to medical file, appointment of a person of trust.
- Special policy for announcement of diagnosis organized by cancer plan 2003-2007: medical time for discussion and explanation of disease and treatment; proposal of treatment with a personalized program of care; social support and care support; articulation with the city medicine.	- Special policy for announcement of diagnosis organized by cancer plan 2003-2007: medical time for discussion and explanation of disease and treatment; proposal of treatment with a personalized program of care; social support and care support; articulation with the city medicine	- Special policy for announcement of diagnosis organized by cancer plan 2003-2007: medical time for discussion and explanation of disease and treatment; proposal of treatment with a personalized program of care; social support and care support; articulation with the city medicine.

PAIN TREATMENT

Portugal	Spain	France
- Ordinance No. 331/2016 – Special payment regime for pain medication. - Law No. 31/2018, of July 18: Rights of persons in the context of advanced disease and end-of--life – accepts deep sedation. Art. 5 (3) "Persons in the context of advanced disease and end-of-life, provided that they are adequately informed of the foreseeable consequences of this option by the responsible doctor and the accompanying multidisciplinary team, are entitled to refuse, under the law, artificial support of vital functions and to refuse to provide treatments that are not proportionate or adequate to their clinical condition and treatments of any nature, which do not aim solely at reducing suffering and maintaining patient comfort or which prolong or aggravate such suffering."	- The right of the patient's autonomy is enshrined in Spanish legal system in Articles 10, 15 and 43 of the Spanish Constitution and, more specifically, in Law 41/2002, of 14 November, which regulates the autonomy of the patient and the rights and obligations regarding clinical information and documentation. - At a regional level, the following must be highlighted: Law 4/2017, of 9 March, on the Rights and Guarantees of Persons in the Process of Dying (Community of Madrid) and Law No. 5/2018 of 22 June on the rights and guarantees of the dignity of persons in the end--of-life process (Autonomous Community of the Principality of Asturias).	- Special article in the public health code for pain management (art L.1105-5 CSP): "Everyone has the right to receive care to relieve their suffering, everywhere on the territory. Pain must be in all circumstances prevented, taken into account, evaluated and treated". - Mobile pain management teams of hospitals can move to other facilities and in home-based networks.

PERSON OF TRUST / PATIENT UNABLE TO CONSENT

Portugal	Spain	France
- Law 15/2014 of March 21 - patient rights legislation - Law 25/2012 of 16 July — Advance Directives, living will and healthcare proxy - Law 49/2018, of august 14 (introduces a new guardianship regime, in accordance with the NY CRPD)	- Law 41/2002, of 14 November, which regulates the autonomy of the patient and the rights and obligations regarding clinical information and documentation: Article 9. - Limits of informed consent and consent by proxy.	- Special article of the public health code: L 1111-6 CSP: every person if the age of majority can designate in writing "a trusted person" who receive the information from health care professionals when the patient is unable to express his or her will. A special form is accessible on the internet. - The designation is free (not compulsory) and revocable at any time. The trusted person informs the care professionals about le will expressed previously.

CARE FOR CANCER PATIENTS

Portugal	Spain	France
- National Health Service provides free, general and universal treatment. - Cancer patients are exempted from fees.	- Initially, both the diagnosis and treatment of the disease are covered by the public health system, which includes consultations, required medical tests, hospitalization, dietotherapy, medication for hospital use and medication for ambulatory use that can be dispensed by the specific health center. - As for the rest of the medication for pharmaceutical acquisition, which is required, a part is co-financed by the Social Security. Therefore, with the contribution of the health card together with the prescription, depending on the person's income, the cost of the medicine will vary. .	- Care reimbursed by social security. - Specific social assistance for serious long-term illness: ALD. Created in 1945, this scheme has been reformed by the Law 2004-810 related to health insurance to facilitate the access to care. - Article L 160-14-3 Social Security code is applicable to prolonged and expensive treatment up to 3 years (100% without money advance). Coverage includes medical act, hospitalization, consultation of health professionals, health products and health related transportation. - Specific treatments for cancer are organized in hospitals (Law 2007-388, of 21 march 2007) and home-based hospitalization are possible according to the needs of patients.

SPECIFIC POLICY FOR CHILDREN

Portugal	Spain	France
- Cancer Plan: Protection of fertility (of adolescents). - Special school program for long-term treatment in pediatric hospital.	- Caring for children affected by cancer or another serious illness. - In 2011, a measure was approved in Spain to support families in which there is a minor diagnosed with cancer or serious illness. It consists on an economic benefit and it compensates the reduction in income that these families have, considering that one of the two parents (they must both be active) reduces his/her working hours to his/her children.	- The 2014-2019 cancer plan pays attention to the needs of children to advance access to innovation, and accompanying the children and their families during and after illness. - Genome sequencing of 2 paediatric tumours ICGC international consortium. - Because of the risk of therapeutic failure, the interregional oncopaediatric resource organ facilitates the inclusion of children in ongoing clinical trial. - Optimization of therapeutic approach Integrated program for cancer research (PAIR) dedicated to pediatric cancers. - Protection of fertility is organized through gametes storages (ART technologies).

RESEARCH AND CANCER

Portugal	Spain	France
- Law 21/2014, 16 April on clinical research. - Opinions of national ethics committee for clinical trials. - Regulation on biobanks. - Data protection Law and GDPR. - Portugal joined the Declaration on linking genomic health data across borders.	- Spain joined The Declaration on linking genomic health data across borders.	- Specific law: legal framework for research since the 1988 Law so called Huriet-Serusclat (Art L 1121-1 and following of the CSP). last update in November 2016. - Several opinions of national ethics committee. - Regulation of biobanks: law 2004-800 defines collections of biological samples (biobanks). Specific regulations are set up for genetic samples, according to the civil code (art 16-10). - Samples and data collected for care purposes can be used for research as far as the subject does not express his or her opposition (art L 1211-2 CSP). - Data protection law and GDPR: express written consent is compulsory for exchanges of data out of the EU. - France did not join the Declaration on linking genomic health data across borders .

CANCER AT WORK

Portugal	Spain	France
- No discrimination – Labour Code. - Some Protective Measures - adaptation of the work station, exemption from extra work, no obligation to provide work between 20:00 and 7:00. - Protection of confidentiality.	- Art. 4.2 c) of the Workers' statute extends the impossibility of discrimination on the basis of disability, "provided that they are fit to perform the work or employment in question".	Patients with cancer: - No discrimination art L 1132-2 of labour code linked with state of health or disability. - Gradual rehabilitation at work after cancer (half time working). - Disability pension when the person loses 66% of his /her working capacity. - Protection of confidentiality of diagnosis to the employer. Cancer caused by work: - Prevention measures for the use of carcinogenic products at work. - Limit values of exposure to chemicals hazards. - Compensation of occupational cancers: Article L 461-1 of Social Security code according to the 20 tables of professional risks. Special fund for compensation of asbestosis (FIVA).

CANCER AND INSURANCE

Portugal	Spain	France
- No discrimination. - Exemption from life insurance when contracting house loans.	- Discrimination on the basis of disability in the taking out of insurance is prohibited.	- No discrimination in access to life insurances according to the health status, nevertheless the insurance can submit the candidate to a medical examination (contract). - AERAS agreement: "secure and Borrow with an aggravated health risk". 3rd cancer plan recommended an amendment "right to be forgotten" (2 September 2015).

END OF LIFE LAWS

Portugal	Spain	France
- Law 25/2012 of 16 July – Advance Directives, living will and healthcare proxy. - Law 31/2018 of July 18 - Rights of persons in the context of advanced disease and end-of-life. - Art. 8 (1): Persons with a life expectancy estimated in weeks or days who present symptoms of distress not controlled by the first-line measures provided for in Article 6 (1), are entitled to receive palliative sedation with sedative drugs duly titrated and adjusted exclusively to the purpose of treating suffering, according to the principles of good clinical practice and leges artis".	- Basic Law 41/2002 regulating Patient Autonomy - Royal Decree 124/2007 regulating the National Register of Prior Instructions and Automated Data File **Autonomous Legal Framework :** - Andalusia: Law 2/2010 on Rights and Guarantees of the Dignity of the Person in the Death Process - Aragón: Law 10/2011 on the Rights and Guarantees of the person in the process of dying and of Death. - Asturias: Law 5/2018 on Rights and Guarantees of the dignity of persons in the end-of-life process - Balearic Islands: Law 4/2015 on the Rights and Guarantees of the person in the process of dying - Canary Islands: Law 1/2015 of Rights and Guarantees of the dignity of the person before the final process of his life. - Basque Country: Law 11/2016 on the guarantee of the rights and dignity of persons in the final process of their lives - Galicia: Law 5/2015 on the rights and guarantees of terminally ill persons - Madrid: Law 4/2017 on the rights and guarantees of the dignity of the person in the process of dying and of death - Navarra: Foral Law 8/2011 on the rights and guarantees of the dignity of the person in the process of death - C. Valenciana: Law 16/2018 on rights and guarantees of the dignity of the person in the end-of-life care process	- The 2005 Law on patient rights and end-of-life, aims to limit unreasonable obstinacy (art L 1110-5 CSP) Physician safeguards the dignity. - A first version of advanced directives is presented in this law (see specific box). - Law No. 2016-87 created new patient rights at the end of life: - Deep and continuous sedation (art L 1110-5-2): alteration of consciousness until death, put in place when the patient has a serious and incurable condition, whose vital prognosis is committed in a short term, and which presents a suffering refractory to analgesic treatments. - Relief of suffering (art. L 1110-5-3): everyone has the right to receive treatment and care to alleviate his or her suffering even if it may have the effect of shortening life. Prevention of suffering in all circumstances.

ADVANCED DIRECTIVES

Portugal	Spain	France
- Law No. 25/2012 of 16 July – Advance Directives, living will and healthcare proxy.	- Basic Law 41/2002 regulating Patient Autonomy. - Royal Decree 124/2007 regulating the National Register of Prior Instructions and Automated Data File.	- Article R 111-17 CSP: "Anyone may make know in writing his or her end-of-life wishes regarding the conditions of prosecution, limitation termination or refusal of treatments or medical procedures". Advance directives are kept in the medical file. Valid indefinitely. Binding for the physician (law of 2016).

PALLIATIVE CARE

Portugal	Spain	France
- Law No. 52/2012, of September 5 (general law which regulates citizens' access to palliative care).	- Spanish Constitution. - Criminal Code (assistance to suicide, omission of the duty to help, coercions, reckless homicide). - General Health Law. - Law 41/2002, Basic Law Regulating Patient Autonomy and Rights and Obligations in Matter of Information and Clinical Documentation. - Law 16/2003, of 28 May: Law on the Cohesion and Quality of the National Health System. - Law 44/2003, of 21 November: Organization of health professions. - Laws enacted in different Autonomous Communities that contemplate the Advance Directives - Deontological Codes.	- Law of 9 June 1999, on palliative care recognizes access to palliative care as a right of the sick person (art L.1 A of the CSP). - Several articles in the public health code implement the device in the sanitary organization in hospitals or at home. Volunteers are trained in end of life assistance. Respect of dignity and privacy. - Provisions concerning patients' entourage (accompanying leave).

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