

2009

Dementia in Europe Yearbook 2009



with a focus on healthcare and decision-making in dementia

Including the Alzheimer Europe Annual Report 2008

Dementia in Europe

Yearbook 2009



**with a focus on healthcare and decision-making
in dementia**

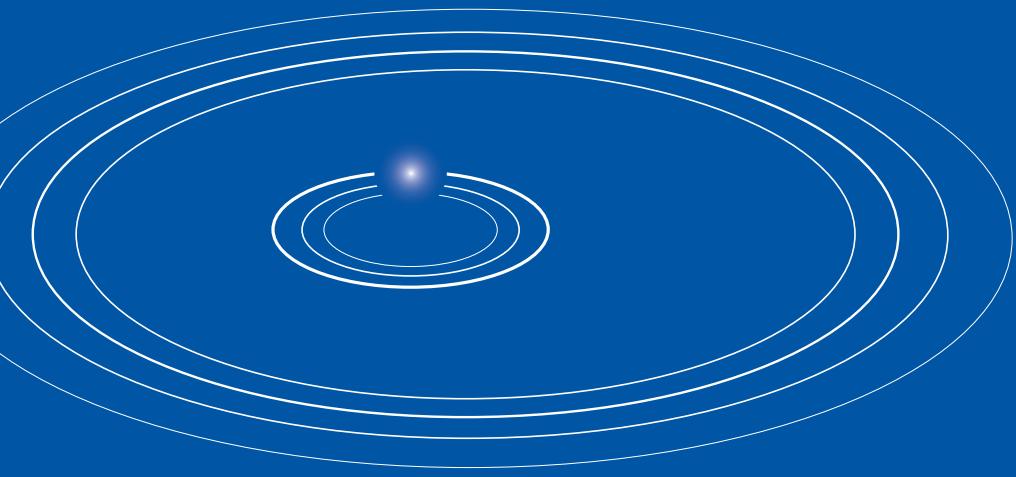
Including the Alzheimer Europe Annual Report 2008

Alzheimer Europe gratefully acknowledges the support it has received from Fondation Médéric Alzheimer for the Alzheimer Europe project on healthcare and decision-making in dementia and for the publication of this Yearbook.



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Forewords

1.1 Vladimír Špidla, European Commissioner for Employment, Social Affairs and Equal Opportunities



There are many dimensions to the challenge of dementia. As I have already written in the foreword to the Dementia in Europe Yearbook of 2007, it is undoubtedly an issue which we all feel uncomfortable about. Indeed, the perspective of growing numbers of persons with dementia represents one of the few aspects of population ageing which cannot be identified as a positive change - even though it is a by-product of the otherwise welcome development in prolonging life expectancies.

I believe it is important to emphasize that the issue of dementia is far more than just a medical problem. Yes, there are more options available for early treatment and prevention (particularly for vascular dementia); and of course, it is to be hoped that future research will further enhance these possibilities. However, we need to face the societal challenge of widespread dementia already today, in many areas of life, rather than wait for a "magic bullet" from the world of science.

Already today, numbers of persons afflicted with Alzheimer's disease and other forms of dementia are at an all-time high. And indeed, many of these people and their families are struggling with a lack of adequate services which would provide high-quality care for them. In addition, even where the care is adequate in all other aspects, it often fails to allow the afflicted persons to continue functioning as social beings to the best of their capacities. It is also evident that various contentious issues remain unresolved in many EU Member States - issues which concern the rights of people with dementia and their legal capacity to take decisions or to anticipate them while still in sufficient control of their cognitive functions.

In this context, it is perhaps noteworthy to highlight the conclusions of the first EU-level conference on Elder Abuse (2008). The discussions on elder abuse and neglect drew the attention of decision-makers to serious risks which exist for elderly people in institutional care as well as from informal carers, including family. These risks also concern other groups of frail and vulnerable elderly people, but they are particularly relevant for those who suffer from dementia. However, it appears that abuse or neglect is not caused only by evil intent of individuals, but also by factors of systemic nature (understaffed services, lack of qualifications and/or knowledge on the part of both formal and informal carers, lack of respite services and inadequate support for families).

In September 2009, the Common Basic Principles and recommendations presented by the Ad Hoc Expert Group on the Transition from Institutional to Community-Based Care placed the emphasis on the careful planning and development of humane, needs-tailored services in the community which should provide an alternative to large residential

institutions. This, again, applies to various categories of persons but it is of clear importance for dementia sufferers.

Finally, while some of the societal issues concerning persons with dementia have fortunately become more visible over the recent period, it cannot be denied that the overall socio-economic context has worsened due to the current economic crisis. It is particularly worrying to see budgets of care services reduced dramatically in some Member States. The care sector, which is already struggling with inadequacy of financial and human resources, is likely to be seriously affected by such decisions. Quality of care for vulnerable individuals (persons with disabilities and elderly people, including dementia sufferers) could be undermined. Given the inevitable demographic development, the care sector is likely to grow rather than to shrink in the long run - but it cannot afford to lose skilled staff today if it is to continue developing towards higher standards of quality.

It is for all these reasons that advocacy for vulnerable groups, including dementia sufferers, will remain of vital importance in the future months and years.

Vladimír Špidla

1.2 *Claude Moraes, Member of the European Parliament and Member of the European Alzheimer's Alliance*



I am delighted to introduce the fourth edition of Alzheimer Europe's "Dementia in Europe Yearbook" which is dedicated to a comparison of the legal systems in the different Member States of the European Union with regard to healthcare decision making by people with dementia. As a member of the Committee on Civil Liberties, Justice and Home Affairs of the European Parliament I recognise the vital importance of the issues which the Yearbook covers, including the issues of consent, the use of advance directives and the rights of people to access to medical information and a diagnosis.

Whilst I am fully aware that these issues are outside the scope of the competences of the European Union, I am also confident that this inventory and comparison of national laws will prove highly useful to policy makers on a European and national level. The exchange of good and best practices in this field will hopefully lead to a greater recognition of the need to respect the dignity and autonomy of people with dementia and to involve them as much as it is possible in all decisions affecting their lives.

As Co-President of the European Parliament Intergroup on Ageing, I warmly welcome the priority given to issues of ageing by different Presidencies of the European Union and I was particularly interested in the conclusions of the recent Swedish Presidency Conference on Healthy and Dignified Ageing which took place in Stockholm in September 2009. This conference clearly highlighted the need for greater collaboration between European countries on these issues, but also for a better coordination between the social and health sectors in all our respective countries.

The recent proposal by the European Commission to launch a European Alzheimer's initiative is equally important. This Yearbook of Alzheimer Europe responds to two of the priorities identified by the European Commission. Commissioner Vassiliou explicitly mentioned the need for an exchange of best practices and a common reflection on the ethical issues posed by dementia. The protection of people with dementia, one of the most vulnerable groups in our societies and the respect of their self-determination and their wishes is clearly an ethical challenge for which national laws have found different solutions.

In the United Kingdom, these issues are dealt with differently in England and Wales and in Scotland, but recent reforms have improved the situation of people with dementia in both areas of the United Kingdom. Scotland introduced key reforms with the Mental Health (Care and Treatment) (Scotland) Act of 2003 and the Adults with Incapacity (Scotland) Act of 2000. These were followed by similar changes in England and Wales through the adoption of the Mental Capacity Act in 2005 and the Mental Health Act in

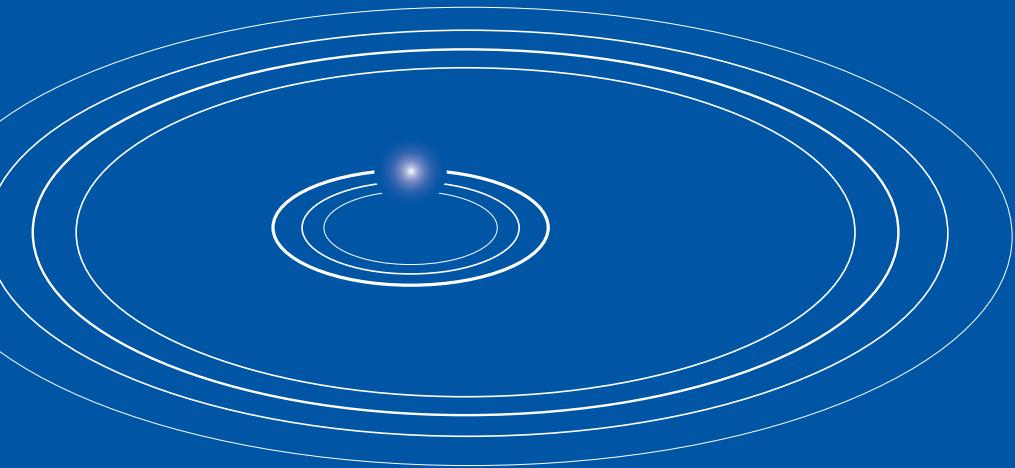
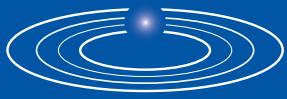
2007. It clearly shows the commitment of the UK government and the Scottish Executive to improve the lives of people with mental health problems including people with dementia and to ensure that wishes of people who may lack legal capacity continue to be respected.

I was also delighted by the announcement of Health Secretary, Alan Johnson who launched a National Dementia Strategy. This five-year plan aims to ensure that "significant improvements are made to dementia services in England across three key areas: improved awareness, earlier diagnosis and intervention, and a higher quality of care." This strategy was developed after consultation with people with dementia and demonstrates how important it is to give a voice to people who often feel disenfranchised.

This latest edition of Alzheimer Europe's Yearbook is fully in line with the various developments described above. As more and more governments recognise the importance of dementia as a public health priority, the need to compare the responses given by governments to the challenges posed by dementia will increase. The findings contained in this Yearbook will provide important information to policy makers from all European countries. I wish Alzheimer Europe continued success with its activities and I look forward to collaborating with the organisation in the future.

Claude Moraes





Introduction



The publication of Yearbooks was an integral part of our “European Collaboration on Dementia – EuroCoDe” project and the first three editions were published with the financial support of the public health programme of the European Commission. The aim of these yearbooks was to compare the situation of people with dementia and their carers in the different Member States of the European Union, as well as in Iceland, Norway, Switzerland and Turkey. The previous editions provided detailed information on the availability and reimbursement of anti-dementia drugs, the prevalence of dementia, the provision of home care and a description of social support systems.

Due to the great interest generated by our previous yearbooks and the positive echo provided by policy makers, researchers and Alzheimer associations, Alzheimer Europe decided to continue this type of publication despite the end of the EuroCoDe project. It therefore gives me great pleasure to introduce the fourth edition of our “Dementia in Europe Yearbook” which is dedicated to present national laws with regard to healthcare decision making by people with dementia and which looks at such issues as consent, the use of advance directives, access to diagnosis and information and end-of-life issues.

With this year’s focus, we decided to revisit the findings of the Alzheimer Europe “Lawnet” project which was carried out in 1998 and 1999 and which resulted in the production of national reports on the legal rights of people with dementia, as well as recommendations on how to improve the legal rights and protection of adults with incapacity due to dementia.

Some of the key priorities identified by Alzheimer Europe in its recommendations were the right for people with dementia to be informed about their diagnosis and the importance of allowing people with dementia to be fully involved in all decisions affecting their lives including through the writing of advance directives or the appointment of representatives.

The two-year “Lawnet” project found significant variations between European countries in how these recommendations were met. Some countries still had mental health legislation dating back to the early 1960’s, while other countries had adopted or were in the process of carrying out fundamental reforms in this area.

Since the initial project only covered the then 15 Member States of the European Union, we felt it important to examine the legislations of the 10 new Members States, as well as other countries covered by Alzheimer Europe member organisations (Croatia, Iceland, Norway, Switzerland and Turkey) and to see whether any progress had been made in the already covered countries in meeting the recommendations that Alzheimer Europe had made.

On behalf of Alzheimer Europe, I would like to thank Dianne Gove, the information officer of Alzheimer Europe for the thorough work she did in gathering the information from 32 European countries and summarising the situation. She was able to do so with a number of legal experts identified by our national member organisations and a detailed list of all contributors is included in the acknowledgements section of the book.

Our thanks also go to Fondation Médéric Alzheimer which shares our passion for improving the lives of people with dementia and ensuring their rights to self-determination and autonomy are respected. We are very grateful to the financial support they provided for the data collection and publication of this Yearbook.

I hope that you will find these national reports of interest and that policy makers and Alzheimer associations will be able to find good and best practices in other countries that may lead to reforms to improve the legal rights of people with dementia in their own countries.

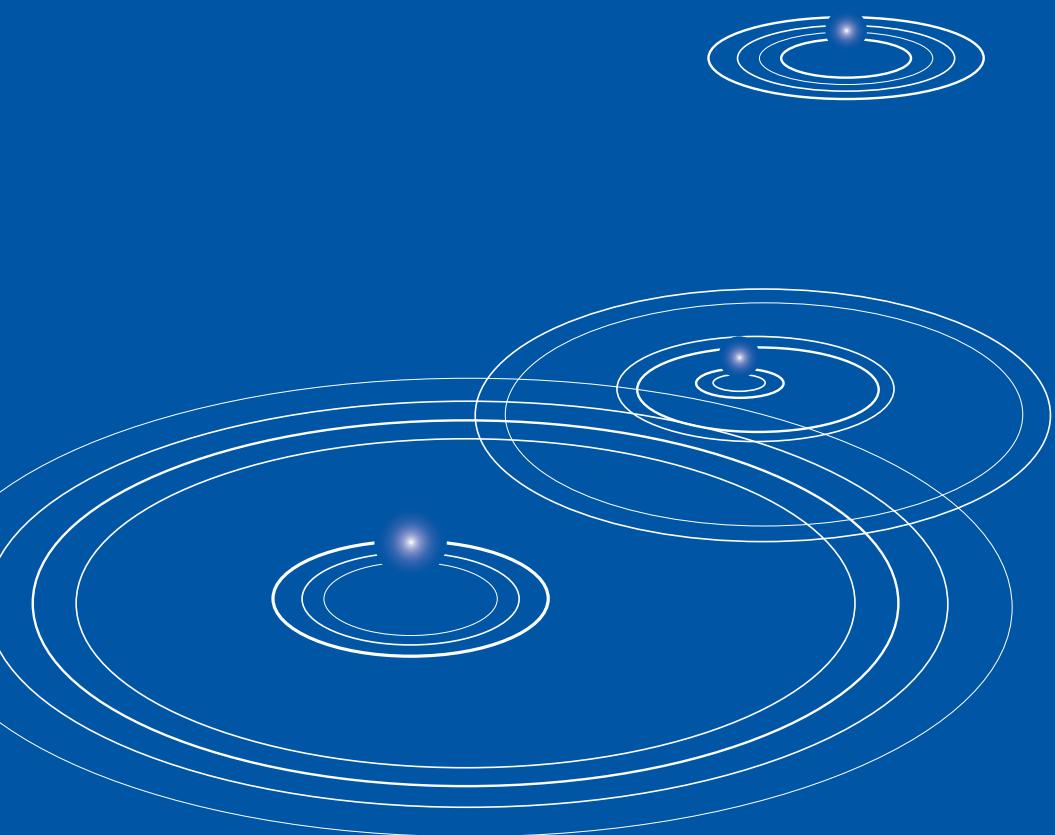
*Jean Georges
Executive Director
Alzheimer Europe*

Note to the readers of this Yearbook

The country descriptions in this Yearbook have been obtained through an extensive literature search, as well as from information provided by representatives of our national member organisations and other individual experts. The reports on the different European countries represent our interpretation of the information we were able to obtain and, to the best of our knowledge, are accurate descriptions of the legal systems in 31 European countries with regard to consent, advance directives, access to information and diagnosis and end-of-life issues for people with dementia.

Nevertheless, we are aware that some of the information obtained may have been out-of-date or misinterpreted by us. Therefore, we invite readers to help us in improving the information contained in this publication. Please feel free to contact us with additional information for those countries for which our reports are incomplete, as well as with any corrections you feel are necessary.





Healthcare and decision-making in dementia – National Reports

3.1 Austria

3.1.1 Consent

3.1.1.1 Consent to medical treatment

Patients must consent to all forms of medical treatment. This is based on the notion of a civil law contract. Consent can be explicitly stated or implicitly implied by the act of turning up for the treatment or consulting the doctor. However, the consent must be related to a specific form of treatment of which the patient is aware of the implications. It is not necessary for consent to be expressed in writing although in practice, in many hospitals patients are asked to sign a form as proof that they were fully informed about the treatment and then consented to it (Leenen et al., 1994).

According to section 8 of Federal Hospital and Convalescent Homes Establishment Law of 1957 (KAKuG), special curative treatment, including operations, can only be carried out with the person's consent. If the person is incapable of consenting, consent can be given by their legal representative. Also, as stated in the section on guardianship (§ 282 of the General Civil Law), the guardians (trustees) are responsible for ensuring the medical and social care of their wards. According to § 283 of the General Civil Law, the Court must give authorisation, if the guardian's consent to treatment is expected to have a lasting or serious impact on the person's health. If the person in question does not resist the treatment, the guardian can also give consent provided that s/he has obtained independent expert advice.

The recent changes in guardianship law, which came into force on 1 July 2007, allow for two other possibilities, namely consent by a next of kin who has been granted agent's authority (Vertretungsbefugnis nächster Angehöriger) or consent by a person (i.e. a trustee) who has a durable power of attorney (DPoA/Vorsorgevollmacht).

For example, it is possible for a competent person to appoint someone to make healthcare decisions on their behalf at a time in the future when they no longer have the necessary capacity to make healthcare decisions themselves. This is called a durable power of attorney for legal representation¹ (referred to hereafter as DPoA). The DPoA only becomes effective when the person granting it loses legal capacity, insight and judgement or the ability to express him/herself (as attested by a medical certificate). A DPoA can cover all medical decisions (including serious medical treatment with lasting effect) provided that it was drawn up before an attorney-at-law, notary public or court and that the power to make such decisions was correctly registered in the document.

The next of kin who has been granted agent's authority can only consent to treatment which is not expected to have a lasting or serious impact on the person's health such as:

- The treatment of straightforward medical conditions (for more complicated conditions/treatment, the consent of an appointed guardian is necessary, or consent by a person who has a durable power of attorney (DPoA));

¹ NÖ Landesverein für Sachwalterschaft und Bewohnervertretung, Durable power of attorney for legal representation, 2007

- The treatment of a psychiatric condition (for simple treatment only; if the person has been interned in a closed department or psychiatric institution, the law on forced internment would apply, or consent by a person who has a durable power of attorney (DPoA));
- Care and welfare decisions.

As next of kin are supposed to make decisions that are in the interests of the person they are representing, the refusal of basic care would not be justified. Basic care does not include artificial nutrition.

Under the Austrian Penal Code (§ 110), anyone who treats another without his/her consent, even if this is in accordance with the rules of medical science, is liable to a prison sentence of up to six months or a fine. The perpetrator will only be prosecuted if the person who received the unauthorised treatment so requests.

3.1.1.2 Consent to treatment under the Internment Law

The Internment Law² contains a section on the treatment of people who are unable to consent (§§ 35-37). Provided that it would not be detrimental to the person's wellbeing, the reason and significance of the treatment must be explained to him/her or his/her legal representative, e.g. to the guardian if one has been appointed with responsibility in this domain, or to a trustee (a person who has a durable power of attorney). An explanation can also be given to the patient's advocate on request.

If the patient is able to understand the reason and significance of a course of treatment and if s/he is able to express his/her will on this issue, treatment cannot be carried out against his/her will. In such cases, certain forms of medical treatment (such as treatment with long-term side effects or surgical intervention) can only be carried out with his/her consent and this must be in writing.

If, on the other hand, the person is unable to understand the reason and significance of the treatment, but has a guardian with the relevant responsibility for treatment decisions, the guardian must give consent. In the case of particular forms of treatment including surgical intervention, consent from the trustee must be in writing. For interventions with serious and lasting effects the Court must give authorisation: If the person requiring treatment is unable to consent and has no legal representative, the Court decides whether treatment should be carried out. Consent to all forms of treatment can be given by the trustee (a person who has a durable power of attorney).

In the case of urgent treatment, consent and/or approval from the Court is not necessary. The ward manager decides on the necessity of the treatment and then informs the legal representative or if the person does not have one, the patient's advocate.

3.1.1.3 Consent in case of emergency

Treatment without consent would not lead to prosecution under § 110 of the Austrian Penal Code if the person was treated on the assumption that postponement of the treatment would have seriously endangered his/her life or health, unless, of course, the supposed danger did not exist and the person providing the treatment would have been aware of this had the necessary care been taken. This is also echoed in the KAKuG.

3.1.1.4 The right to refuse treatment

In the exact same manner as patients (or their representatives) must consent to all forms of medical treatment, they can refuse treatment. If a guardian's refusal of treatment would endanger the health of the person in question consent to treatment can be given by the Court. Treatment without consent is forbidden by the Penal Code.

3.1.1.5 Consent to non-conventional treatment

For certain forms of non-conventional treatment (e.g. craniosacral therapy or Traditional Chinese Medicine), the aforementioned rules for consent apply. However, some forms of non-conventional treatment (e.g. mental healing or faith healing) are not officially recognised as treatment and would not be offered in the context of the official healthcare system.

3.1.1.6 Consent to organ donation

Article 62a of the KAKuG stipulates that it is illegal to remove the organ of a person who made a declaration before his/her death expressly refusing organ donation. Such a declaration could equally be made by a person's legal representative.

3.1.1.7 Consent to clinical trials

Participation in clinical trials is governed by the Medicaments Law (No. 185) of 1983 (Leenen et al., 1993). Participants must consent to their participation and such consent is only valid if they are capable of managing their own affairs, able to understand what is involved, aware of the significance of the trial and aware of any dangers involved. If a person fulfils these conditions and decides to participate, s/he retains the right to withdraw from the trial at any time. A person who has been interned (in a psychiatric ward or a nursing home) cannot give consent to clinical trials. According to § 284 of the General Civil Law, a guardian can only give consent in the exceptional case that the treatment provides immediate benefit to the health of the person in question. Authorisation from the Court is necessary.

Paragraph 8c of the KAKuG states that founders of hospitals and clinics are obliged to set up ethics committees to assess clinical tests of medicines and medical products and the application of new medical methods in the hospital or clinic. Assessments must pay particular attention to the people taking part in the research, the relationship between the target and the scientific meaningfulness and between usefulness and risk, the manner in which experimental subjects are selected, the way information is given and consent obtained and the precautions against possible damage to participants.

3.1.1.8 Consent to research

Consent to research follows the same rules as consent to clinical trials.

3.1.2 Advance directives/living wills

3.1.2.1 The legal status of advance directives in Austria

According to § 10 of the Hospital Establishment Law of 1957 (KAKuG), it is obligatory when recording a patient's case history in hospitals and clinics to document instructions from the patient regarding certain forms of treatment which should not be carried out in the case of future incapacity. These instructions must then be taken into account by doctors in the event of the patient's future incapacity.

In Austria, it is possible to write an advance directive (sometimes called a "living will") ("Patientenverfügung") and/or to appoint a trusted person to act on one's behalf ("Vor-sorgevollmacht"/DPoA). The duties of the trusted person may be limited to financial, administrative and/or care issues, but may also (or alternatively) cover healthcare decisions.

On 1 July 2006, the 55th Federal Act on Living Wills (the "Patientenverfügungsgesetz – PatVG") came into force. This act regulates the requirements and effectiveness of living wills. The law divides living wills into those that are binding and those that are non-binding.

3.1.2.2 Conditions surrounding the writing, validity and registering of an advance directive

A person making a living will should have the capacity for insight and judgement (§ 3). In a binding living will, any medical treatments that are to be refused must be concretely described or be clear from the overall context of the document. It must be clear that the person making the living will appropriately evaluates the consequences of the living will (§ 4).

Before writing the living will, the person must consult a doctor in order to obtain information about the nature and consequences of the living will for medical treatment. The doctor providing such information must also confirm the person's capacity for insight and judgement by indicating his/her name and address and signing the document. S/he must also confirm that the person has appropriately evaluated the consequences of the living will and give examples to demonstrate in what way (§ 5).

If the doctor providing information in this context is of the opinion that the patient does not have the necessary insight and judgement to draw up a living will, s/he shall document this, if applicable, in the patient's medical history (§ 14).

§ 10 states that a living will is invalid if it is not based on a free and well-considered declaration, or if it has been initiated by error, fraud, deception or on physical or mental

pressure. In addition, it is considered invalid if its content is legally unacceptable, if the state of medical science has changed with regard to something mentioned in the living will since it was written and if it has been revoked or the patient suggests that it is no longer valid.

According to the law proposal, a relevant advance directive can also be made orally by a hospitalised patient. For non-hospitalised patients who have not personally written or signed their advance directive, it must contain the signature of a doctor who certifies that s/he has provided the person with the relevant information relating to the decisions made by the patient.

The informing and attending doctor must include the living will in the patient's clinical records. If the living will is drawn up outside the hospital setting, the doctor must include it in the medical history (§ 14).

3.1.2.3 What an advance directive can cover

The federal act on living wills does not explicitly state what can be included in the living will but it does state that it can contain additional comments such as the designation of a specific confidant, the refusal of contact with a specific person or the obligation to inform a specific person (§ 11).

The living will cannot be used to refuse treatment that has been imposed on a person by specific legal provisions (§ 13).

3.1.2.4 Obligation to comply with instructions contained in an advance directive

The living will is considered binding if it was drafted in writing, if the date was indicated in the presence of a lawyer, a notary, or a legally trained associate of the patient advocacy, and if the patient was informed about the consequences of the living will as well as about the possibility to revoke it at any time. The person witnessing the dating of the document must also personally sign the document (§ 6).

If the living will does not fulfill the above-mentioned conditions, it is considered as non-binding but must still be taken into account when trying to establish a patient's will. The closer the living will is to fulfilling the conditions, the more it will be taken into account when trying to establish the patient's will (§§ 8 and 9).

If emergency treatment is needed and taking time to search for a living will would seriously endanger the life or health of the patient, doctors can take the necessary measures (section 12).

3.1.2.5 Amending, renewing and cancelling advance directives

A living will is valid for 5 years from the date it was signed unless a shorter period of time was specified. It can be renewed for a further five-year period as long as the formal requirements previously mentioned have again been fulfilled. Every amendment is

treated in the same way as a renewal and the expiry date is reset for the entire living will. It does not lose its binding character once the patient is unable to renew it due to incapacity to understand, judge or express him/herself (§ 7).

A DPoA can be revoked at any time, even after the person who made it has lost capacity, insight or judgement.

3.1.3 Access to information/diagnosis

3.1.3.1 The right to be informed

§ 5 of the Federal Hospital Establishment Law of 1957 (KAKuG) focuses on patients' rights. It is stated that patients must be informed of their rights and that they are entitled to an explanation and information on possible forms of treatment, as well as on the risks involved. Furthermore, the patient can request that s/he (or alternatively someone in a position of trust) be given medical information by a doctor who is authorised to exercise his/her profession independently. This information should be given in a clear and considerate manner.

The doctor's obligation to inform the patient is linked to the obligation to obtain consent in that the patient cannot give informed consent unless s/he has been adequately informed. As a result of jurisprudence, several guidelines have been developed. The information must be provided in a way that the patient can understand and that will not endanger his/her wellbeing. It should be appropriate in respect of his/her mental capabilities, state of mind, level of education, knowledge and intelligence. Furthermore, the amount and detail of the information given should correspond to the scale of the treatment or intervention in that minor treatment or operations do not require as much detail as more serious ones (Leenen et al., 1993).

3.1.3.2 Access to medical files

§ 5 of the Federal Hospital Establishment Law of 1957 (KAKuG) states that patients must be informed of their rights and that one of these rights is to examine their case history. This right to see records kept by the doctor or hospital stems from a decision taken by the Supreme Court on 25 May 1984 (1 Ob 550/84) (Leenen et al., 1993). Access to a medical file can, however, be refused on therapeutic grounds, if the person is interned in a psychiatric ward and access could constitute a severe risk to the patient's health.

3.1.3.3 The right to designate another person to be informed on one's behalf

Whilst he/she still has capacity, a patient can request that someone in a position of trust be given medical information by a doctor on his/her behalf.

3.1.3.4 The doctor's right to withhold information

According to § 36 of the Internment Law, as an exception to the rule to give all information to the patient, the doctor can withhold information that will cause severe risk to patients' health, for example a non substantiated tentative diagnosis. As a result of juris-

prudence and legal doctrine information can be withheld in similar cases concerning patients outside psychiatric hospitals or wards.

3.1.3.5 The patient's right to refuse information

With regard to withholding information on the grounds that the patient does not want it, a Supreme Court Ruling of 19 December 1984 (3 Ob 562/84) declared that such a decision could only be made on the basis of a conversation with the patient and if necessary with his/her close relatives.

3.1.3.6 Confidentiality/disclosure of information to other people

The Data Protection Law (2000 and subsequent amendments) states that every person has the right to respect concerning his/her private and family life, residence and mail.

It is more specifically dealt with in § 121 of the Penal Code which protects patients against unlawful disclosure by health professionals of information, particularly that relating to their state of health. The state of health of a person is understood to include conditions relating to the physical or mental condition of a person, including past illnesses and suffering. The disclosure of such information to other people, even those bound by secrecy laws, constitutes damage to the patient.

Secrecy is further covered by § 9 of the KAKuG and § 54 of the 169th Federal Physician's Law of 1998. The latter states that:

"the doctor and his/her assistants are bound to secrecy in respect of all secrets that are confined to them or become known to them in the exercise of their profession".

It then goes on to mention exceptions to this rule, e.g. in the case of suspected abuse, in order to protect the higher interests of public healthcare or the administration of justice and with regard to the payment of medical fees. Paragraph 9 of the KAKuG applies to everyone employed in a hospital or clinic and refers to the kind of information protected. It states:

"Persons employed in hospitals/clinics and members of commissions under § 8 are subject to the obligation of secrecy, where they are not already obliged to such secrecy by other legal provisions or provisions relating to their conditions of service. The obligation of secrecy shall extend to all circumstances relating to the illness, and personal, financial and other circumstances of the persons in care which have become known to the employees of the institution in the course of their professional duties."

3.1.4 End-of-life care and issues

3.1.4.1 Euthanasia

Active/direct euthanasia involving the administration of treatment which results in the ending of a person's life is illegal, even if it is carried out in order to hasten a painful death. Nevertheless, doctors are not obliged to prolong a dying person's life at all costs. Therefore, passive euthanasia, which involves the withholding of life-preserving measures

(e.g. resuscitation, blood transfusions and artificial feeding etc.), is not illegal if the illness is irreversible or involves damage which will inevitably lead to death. Indirect euthanasia which usually involves the administration of treatment intended to relieve intense pain and can result in the shortening of a person's life, is not illegal.

3.1.4.2 Assisted suicide

Paragraph 78 deals with the issue of assisted suicide. It states that whoever leads another to commit suicide or assists the person in doing so, will receive a prison sentence of six months to five years.

3.1.4.3 Non assistance to a person in danger

According to § 95 of the Penal Code, whoever does not help a person whose life is in danger or who risks serious bodily injury or damage to his/her health, will receive a prison sentence of up to 6 months or a fine. In case such failure to provide assistance results in the death of the endangered person, the prison sentence will be of up to 1 year or a fine (unless such assistance could not have been reasonably expected).

3.1.4.4 Murder

According to § 75 of the Penal Code, whoever kills another person will receive a prison sentence of between 10 and 20 years or a life sentence.

3.1.4.5 Murder at the request of the victim

Paragraph 77 of the Penal Code states that anyone, who kills another on that person's serious and insistent request, will be condemned to a prison sentence of between six months and five years.

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Patientenvertretung der Tiroler Landeskrankanstalten Ges.m.b.H (1997), *Die Ärztliche Aufklärungspflicht*

3.2 Belgium

3.2.1 Consent

3.2.1.1 Consent to medical treatment

Pursuant to Article 8 § 1 of the Law of 22 August 2002 on Patients' Rights, consent is required for medical acts that intrude on a person's physical integrity (Leenen et al., 1993). Such consent can be implied except in the case of major interventions. At the request of the patient and with the agreement of the physician, or alternatively, at the request of the physician and with the agreement of the patient, the consent is recorded in writing and put in the patient's medical file.

Consent may be given on behalf of a person who is suffering from a mental disorder or who is unable to express his/her will either by a formally designated legal representative or by a family member in his/her role as the patient's natural protector.

The issue of consent is also covered in the Code of Medical Ethics³. Article 30 of the Code states that if a patient is incapable of giving his/her consent and it is impossible or inappropriate to obtain the consent of his/her legal representative, the doctor must proceed with treatment as dictated by his/her conscience.

By virtue of Article 13 § 2 of the Law of 22 August 2002 on Patients' Rights, the patient can continue to exercise his/her rights for as long as he/she is capable of understanding.

Article 14 § 1 of the same law states that a patient can, while still capable of understanding, appoint a "mandatary" to exercise rights under that law on the patient's behalf in the event of subsequent inability of the patient to exercise such rights. For this purpose, a special mandate must be drawn up in writing, dated and signed by both the mandatary and the patient. In the absence of such a mandatary, the patients' rights are exercised by, in order of priority, the cohabiting spouse, the cohabiting legal partner, the cohabiting partner in fact, an adult son or daughter, a parent, or an adult brother or sister. For simplicity, the mandatary or other person determined by Article 14 § 1 will be referred to in the rest of this chapter as "the Article 14 Representative". It should be emphasised that this is not the same as a "provisional administrator" who can be appointed by the courts to manage a person's property pursuant to Article 488 bis of the Belgian Civil Code, or the "legal representative" appointed by the courts to manage all the affairs of a person who has been declared "legally incapable" pursuant to Article 489 of the Belgian Civil Code.

3.2.1.2 Consent in case of emergency

In cases of emergency where there is uncertainty as to the existence or not of wishes expressed by the patient or the Article 14 Representative, Article 8 § 5 of the Law of 22 August 2002 on Patients' Rights provides that the physician must intervene in the best interests of the patient's health. Such emergency situations must be noted in the patient's personal file kept by the physician.

3.2.1.3 The right to refuse treatment or withdraw consent

By virtue of Article 8 § 4 of the Law of 22 August 2002 on Patients' Rights, the patient has the right to refuse a particular treatment or to withdraw his prior consent at any time. The refusal or withdrawal of consent is recorded in writing at the request of either the patient or the physician, and put in the patient's medical file. However, the fact that the patient has refused a particular treatment does not affect his/her rights under Article 5 of the same law, notably the right to quality services corresponding to his/her needs, and in full respect for his/her human dignity and autonomy.

3.2.1.4 Consent to non-conventional treatment

The Law of 22 August 2002 on Patients' Rights applies to all services provided by a professional physician with the objective of (i) promoting, determining, conserving, restoring or improving the state of health of a patient, and/or (ii) accompanying the patient at the end of life. The physician can be either a medical practitioner qualified to provide conventional treatment in accordance with the law of 10 November 1967 on the Medical Professions, or a practitioner of non-conventional medicine within the meaning of the Law of 29 April 1999 on non-conventional practice in the medical, pharmacy, physiotherapy, nursing and paramedical professions. Thus the provisions described above in relation to consent to medical treatment are applicable equally to non-conventional treatment covered by the Law of 29 April 1999.

3.2.1.5 Consent to the donation of organs and/or human tissue

The donation of organs and human tissue is regulated by the Law of 13 June 1986 on the Transplant of Human Organs. This Law makes a distinction between the taking away of organs and human tissue (i) when the donor is still living and (ii) after the donor has died.

In the first situation, fully informed consent must be obtained either from the donor himself/herself or, if he or she is incapable of expressing consent by reason of his/her mental state, from any legally appointed mandatory or the Article 14 Representative (Article 6 § 2).

In the case of a deceased person, organs and human tissue may be taken, without prior consent, from the body of any deceased person registered in the population register, or registered for at least six months in the foreigners' register (Article 10 § 1). However, persons can refuse the removal of organs or human tissue after their death by prior formal notification of such refusal to their local authorities (Article 10 § 3). Persons unable to express their refusal by reason of their mental state are represented by their legal representative, provisional administrator or closest relation for this purpose (Article 10 § 2).

In the case of deceased persons not registered in either the population register or the foreigners' register, the removal of organs or tissue is not permitted unless the deceased person has expressed his/her prior consent, duly proven (Article 10 § 1).

3.2.1.6 Consent to research and participation in clinical trials

The conduct of clinical trials and experiments on human beings is regulated by the Law of 7 May 2004 on Experiments on Human Beings, and also falls within the scope of Article 91 of the Code of Medical Ethics.

A person cannot be subjected to scientific observation or used purely for research purposes. A person cannot be subjected to procedures which could cause the slightest inconvenience and which are not therapeutically beneficial without his/her fully informed consent in writing, or in the case of a person unable to give his/her consent, without the fully informed consent in writing of his/her guardian. In the case of incurable illness it does not have to be demonstrated that the research will be therapeutically beneficial.

Article 6 of the Law of 7 May 2004 on Experiments on Human Beings requires that consent must also be obtained in writing by the physician for a patient's participation in a clinical trial. For persons suffering from a mental disorder or who are unable to express their consent, Article 8 provides, in effect, that the Article 14 Representative can give the consent. At any time, the patient or the Article 14 Representative can decide to quit the clinical trial.

Any biomedical research or clinical trial must be approved by the medical ethics committee of the National Council of the Order of Physicians (Articles 11 ff.).

3.2.2 Advance directives and healthcare proxies

3.2.2.1 The legal status of advance directives

As a general rule, Belgian law does not use the term "advance directive" or "advance declaration" except in the specific context of the Law on Euthanasia of 28 May 2002. There are many other laws, however, which require prior consent for certain acts, notably the Law on Patient's Rights, the Law on Transplant of Human Organs, and the Law on Experiments on Human Beings. The term "Advance Directive" is used colloquially to describe a document in which a person seeks to deal with some or all of such consents (or refusal of consent) in advance, and especially to deal in advance with the case where the person becomes incapable of expressing his/her wishes. In addition, an "Advance Directive" can also appoint another person as the first person's Article 14 Representative for the purpose of consenting to treatment in the future, and/or as a personal confidant.

Thus the legal status of such an advance directive has to be examined disposition by disposition. The validity of each disposition will depend on the relevant law governing that disposition (consent to treatment, consent to participation in experiments, appointment of a representative, etc.)

3.2.2.2 Conditions surrounding the writing, validity and registration of an advance directive

For the reasons explained in section 3.2.2.1 above, the conditions of validity of an advance directive have to be examined separately for each disposition, having regard for the law governing that disposition, namely:

- consent to or refusal of certain types of treatment, including non-conventional treatment – see Sections 3.2.1.1, 3.2.1.3 and 3.2.1.4 above;
- designation of the Article 14 Representative to act on the patient's behalf if the patient should become incapable of acting him/herself – see Section 3.2.1.1 above;
- consent to donation of organs or tissue while still alive – see Section 3.2.1.5 above;
- consent to participation in clinical trials - see Section 3.2.1.6 above;
- formulation of an advance declaration concerning euthanasia in the event that the patient becomes unconscious – see Section 3.2.4.3 below.

3.2.2.3 What an advance directive can cover

For the reasons explained in section 3.2.2.1, an advance directive can cover anything for which the law requires prior consent or appointment, namely:

- consent to or refusal of certain types of treatment, including non-conventional treatment – see Sections 3.2.1.1, 3.2.1.3 and 3.2.1.4 above;
- designation of an Article 14 Representative to act on the patient's behalf if the patient should become incapable of acting him/herself – see Section 3.2.1.1 above;
- consent to donation of organs or tissue while still alive – see Section 3.2.1.5 above;
- consent to participation in clinical trials - see Section 3.2.1.6 above;
- formulation of an advance declaration concerning euthanasia in the event that the patient becomes unconscious – see section 3.2.4.3 below.

3.2.2.4 Obligation to comply with instructions contained in an advance directive

For the reasons explained in section 3.2.2.1 above, the question whether the physician is obliged to comply with instructions contained in an advance directive has to be examined by reference to the type of instruction under consideration.

The underlying principle of Article 8 § 4 of the Law of 22 August 2002 on Patients' Rights is that the wishes of the patient must be respected. Thus if the patient's written instructions refuse a certain treatment the physician must comply. However, the fact that the patient may have refused a particular treatment does not affect his/her rights under Article 5 of the same law, namely a right to quality services corresponding to his/her needs, and in full respect for his/her human dignity and autonomy.

It follows also from this underlying principle that the scope of a patient's consent, if any, to donation of organs must not be exceeded, as also the scope of his/her consent, if any, to take part in clinical trials.

It should be noted that a physician is under no legal obligation to comply with a patient's advance declaration concerning euthanasia. The Law on Euthanasia of 28 May 2002 merely provides the physician with protection against criminal prosecution if he/she carries out an act of euthanasia within the strict conditions laid down by the law. Thus the question whether the physician complies with the patient's advance declaration in this respect is solely a matter of professional ethics for the physician.

3.2.2.5 Amending, renewing and cancelling advance directives

Consent or authorisation discussed above can be revoked at any time in writing signed by the patient. The amendment or renewal of consent or appointment would have to be accomplished respecting the same formalities as for the original consent or appointment. Regarding an advance declaration concerning euthanasia, the Law on Euthanasia of 28 May 2002 simply says that the declaration can be withdrawn at any time, but does not prescribe any formalities for such withdrawal. In practice, if a patient were to do anything that cast doubt on his/her advance declaration concerning euthanasia, the physician would not act.

3.2.3 Access to information/diagnosis

3.2.3.1 The right to be informed

Pursuant to Articles 7 and 8 of the Law of 22 August 2002 on Patients' Rights, patients have the right to be informed about their medical situation and any treatment by the physician. There are also a few provisions in the Code of Medical Ethics regarding access to information. Article 29, for example, states that it is the doctor's duty to inform the patient of the reasons for diagnostic or therapeutic interventions which he/she proposes. It does not state that the patient must be informed of the diagnosis, but Article 33 states:

"The physician informs the patient in due course on the diagnosis and prognosis, including serious and fatal prognosis. For this purpose the physician must take into account the patient's wishes. In any case, the physician assures the patient a continued treatment and appropriate follow-up. At the same time, the physician must inform the patient's entourage accordingly unless the patient objects."

3.2.3.2 Access to medical files

Article 9 § 1 of the Law of 22 August 2002 on Patients' Rights provides that a patient has the right to require his physician to keep a file with due care, up to date and in a safe place. The patient may provide his/her physician with documents to be kept in the medical file. Moreover, there are many provisions of the various laws in the medical field which require a physician to place a record of certain information in a patient's medical file. Articles 38 and 39 of the Code of Medical Ethics also require that a physician should in

principle keep a medical file on each patient and is responsible for determining who has access to all or part of the information kept in it.

Article 9 § 2 of the Law of 22 August 2002 on Patients' Rights also provides that a patient has the right to consult his medical file. Access should be granted in principle as quickly as possible, and in any case no later than 15 days of the patient's request. The patient's right of access does not extend to personal annotations made by the physician nor to information concerning third parties.

3.2.3.3 The right to designate another person to be informed on one's behalf

Article 7 § 2 of the Law of 22 August 2002 on Patients' Rights provides that a patient may request in writing that information about his/her state of health and its likely evolution be communicated to a personal confidant. Such written request as well as the identity of the personal confidant must be put in the patient's medical file.

Article 9 § 2 of the Law of 22 August 2002 on Patients' Rights provides that the patient can consult his/her medical records in the physician's possession. In exercising the rights to obtain information and consult his/her medical records, pursuant to the Law on Patients' Rights, the patient may be assisted by a personal confidant designated by him/her. If this personal confidant is a physician, the latter can also consult the personal annotations made by the physician treating the patient.

Articles 7 § 2 and 9 § 2 deal specifically with the designation of a personal confidant to assist the patient in exercising the right to be informed and the right to access the medical file. This presupposes that the patient's mental state does not prevent him/her from exercising such rights. If the patient's mental state does prevent him/her from exercising such rights, it would fall to the Article 14 Representative to exercise those and other rights on the patient's behalf.

3.2.3.4 The doctor's right to withhold information

A physician may refuse to provide information to the patient about his/her medical situation and diagnosis, if informing him/her about the medical situation and/or diagnosis could have a negative effect on his/her health. However, as provided by Article 7 § 4 of the Law on Patients' Rights, such refusal is only allowed if the physician has requested the opinion on this issue from another physician.

When the medical file contains information the communication of which might gravely prejudice the patient's health (see Section 3.2.3.1 above), the patient must exercise his/her right of consultation through a personal confidant who is also a physician (see Section 3.2.3.3 above).

3.2.3.5 The patient's right to refuse information

Article 7 § 3 of the Law of 22 August 2002 on Patients' Rights provides that a patient may request in writing not to be informed of his/her state of health and likely evolution. The

physician must comply with such request unless so to do would cause grave harm to the patient or to a third person, in which case the physician must consult another physician on this subject and also any personal confidant designated by the patient.

3.2.3.6 Confidentiality/disclosure of information to other people

Doctors are bound to secrecy by the provisions of chapter V of the Code of Medical Ethics. This obligation extends to everything that the doctor sees, learns of, notices or discovers through the exercise of his/her duties. Nevertheless, Article 458 of the Penal Code, which also establishes professional secrecy, provides exceptions to this obligation, such as the obligation to provide information to the courts (Leenen et al., 1993).

Article 10 § 1 of the Law of 22 August 2002 on Patients' Rights provides that the patient is entitled to the protection of privacy ("private life") on the occasion of the intervention of a physician, notably in matters relating to his/her state of health. The patient has the right to "intimacy". Except with the patient's agreement, only persons whose presence is justified can attend during care, examinations and treatment provided by a physician.

The principle of confidentiality does not prevent a patient from appointing a personal confidant for the purposes of exercising the patient's right to information or the right to consult his/her medical file (see Section 3.2.3.3 above).

3.2.4 End-of-life care and issues

3.2.4.1 Palliative care

Article 2 of the Law of 14 June 2002 on Palliative Care lays down the general principle that every patient must be able to benefit from palliative care as he/she approaches the end of life. Palliative care is defined "... all care or treatment given to a patient afflicted with an illness likely to lead to death once the illness ceases to respond to curative therapy". Article 2 also states that the first objective of palliative care is to provide the patient and those close to him/her with the best quality of life possible and maximum autonomy.

Article 7 of the same law provides that every patient has the right to information concerning his/her state of health and the possibilities for palliative care. The physician treating the patient must communicate this information in appropriate terms having regard for the patient's situation, his/her wishes and his/her faculties of understanding. Article 95 of the Code of Medical Ethics complements this by providing that a physician must inform the patient at the appropriate time of the impending end of his/her life, and of the assistance that can be provided. In reply to any request on the subject, the physician must explain to the patient the various steps that he/she may take, such as the appointment of a representative, the refusal of certain forms of treatment, and the preparation of an advance directive. In particular, the physician must inform the patient of his/her right to receive palliative care. If the physician decides upon a course of treatment or care, he/she must explain this to the patient and give the patient adequate time to obtain a second opinion. Further, the physician and the patient should discuss and agree on the

persons who must be informed of the patient's situation, and the extent of such information. Article 7 of the Law of 14 June 2002 on Palliative Care also provides that the patient must give fully informed consent for medical examination and treatment. This law does not make any provision for representation of the patient in case of inability to mark his/her consent due to his/her mental situation.

Article 96 of the Code of Medical Ethics states that when a person is in the last stages of his/her life, the doctor must provide him/her with all the moral and medical support possible in order to alleviate psychological and physical suffering and to preserve his/her dignity.

3.2.4.2 Special leave for carers in paid employment

In addition, Article 100bis of the Law of 22 January 1985 with regard to social provisions provides for special leave for employees who care for terminally ill persons. The term of such special leave amounts to one month and can be extended by the same amount. In order to benefit from this special leave it is not necessary that the person being cared for be a family member. When someone wants to use this special leave, his employer must be notified and a special certificate issued by a physician must be filed.

3.2.4.3 Euthanasia

A distinction is sometimes made between passive euthanasia, also known in Belgium as "orthothanasie", and active euthanasia.

For example, the giving of palliative care is sometimes considered as "passive euthanasia" if it results in shortening a patient's life. The providing of palliative care is not considered to constitute a criminal offence, provided the patient is informed of the treatment and of its consequences, and marks his/her consent in writing. The intention is not to cause death, but to care for the patient.

On the other hand, intentionally depriving a person of food or care to such an extent as to compromise his/her health when, by reason of his/her physical or mental state that person is unable to provide for him/herself is a criminal offence under Article 425 of the Penal Code, whether or not the person dies as a result. Such action would also be considered as quite unethical and could not fall within the "safe harbour" provisions of the Law on Euthanasia of 28 May 2002.

From a legal point of view, the term "euthanasia" can only be used as defined by Article 2 of the Law on Euthanasia of 28 May 2002 - "an act carried out by a third party which intentionally terminates the life of someone at the latter's request". Such an act would normally constitute the offence of voluntary homicide or homicide with premeditation ("assassinat") – see sections 3.2.4.4 and 3.2.4.6 below – unless it was carried out within the strict conditions of the Law on Euthanasia of 28 May 2002. The innovation introduced by the Law on Euthanasia of 28 May 2002 was to remove the risk of prosecution and pro-

vide a “safe harbour” in the case where a physician carries out an act of euthanasia on a patient after respecting all the procedures and conditions laid down by this Law.

The Law of 28 May 2002 provides for two procedures, the first where the physician acts on the basis of a written request formulated directly by the patient, and the second where the physician acts on the basis of an advance directive.

Under the first procedure, the patient must formulate the request for euthanasia in a written document, signed and dated. If the patient is not in a condition to do this, the request can be made by an adult person chosen by the patient, but who must have no interest in the patient’s death. The request is put in the patient’s medical file. The patient may withdraw his/her request at any time, in which case it is removed from his/her medical file.

The physician must ensure that:

- “the patient has attained the age of majority or is an emancipated minor, and is legally competent and conscious at the moment of making the request;
- the request is voluntary, well-considered and repeated, and is not the result of any external pressure;
- the patient is in a medically futile condition of constant and unbearable physical or mental suffering that can not be alleviated, resulting from a serious and incurable disorder caused by illness or accident.”

In addition the physician must:

- Inform the patient of his/her state of health and life expectancy, discuss with him/her possible workable therapies as well as the possibilities offered by palliative care. The physician must reach, with the patient, the firm conviction that there is no other reasonable solution in the circumstances, and that the patient’s request is entirely voluntary.
- Satisfy him/herself of the persistence of the patient’s physical or psychological suffering and of the patient’s continuing desire, over a reasonable period, for euthanasia to be carried out.
- Consult another independent physician as to the serious and incurable nature of the patient’s affliction.
- Consult with the members of any team of carers in regular contact with the patient.
- If the patient so wishes, consult with close relations designated by the patient.
- Check that the patient has had the opportunity to discuss his/her request with anyone he/she wished to.

Where the physician considers that death will not occur naturally in a short time, he/she must consult with another physician specialised in the pathology concerned and discuss the results of such consultation with the patient. In any event, the physician must allow at least one month between the patient's written request and the carrying out of the act of euthanasia.

Under the second procedure, the physician carries out the act of euthanasia on the basis of an advance declaration. For this purpose the Law of 28 May 2002 provides that an adult (or emancipated minor) person may draw up an advance declaration in writing expressing his/her desire that his/her physician carry out an act of euthanasia where the physician finds that:

- the patient suffers from a serious and incurable disorder, caused by illness or accident;
- the patient is no longer conscious;
- this condition is irreversible given the current state of medical science".

In the case of advance declaration, the patient must have made or confirmed the request no more than five years before losing the ability to express his/her wishes and it must have been added to the patient's medical file. The document must be written, dated and signed in the presence of two adult witnesses, and any appointed healthcare representative (or proxy). At least one of the witnesses must have no material interest in the person's death. A form of advance declaration is annexed to a Royal Decree of 2 April 2003.

Article 4 § 2 of the Law on Euthanasia of 28 May 2002 provides a "safe harbour" for a physician who carries out an act of euthanasia on a patient pursuant to an advance declaration where the patient is suffering from an accidental or pathological affliction which is serious and incurable, the patient is unconscious, the situation is irreversible in the light of current science and the physician respects all the conditions laid down by Article 4 § 2. These conditions are as follows:

- The physician has consulted another physician on the irreversibility of the patient's medical situation and the results of such consultation are communicated to the patient's personal confidant, if any. The second physician must be independent of both the patient and the first physician, and must be competent in the pathology concerned.
- If there is a medical team that was in regular contact with the patient, the physician must consult with this team or its members.
- If the advance declaration designates a personal confidant, the physician must consult with this person and also with any persons close to the patient designated by the personal confidant.

3.2.4.4 Assisted suicide

A person who knowingly and consciously assists another person in committing suicide could commit one or more of the following offences, depending on the circumstances, and the degree of knowledge or premeditation involved. These offences are:

- homicide with the intention of causing death – Article 393 of the Penal Code;
- premeditated homicide or “assassinat” – Article 394 of the Penal Code;
- failure to come to the assistance of a person in danger – Article 422 bis of the Penal Code (see also Section 3.2.4.5 below).

There would be a valid defence, however, if the assistance to commit suicide were provided by a physician as part of intentionally administering an act of euthanasia carried out in accordance with the strict terms of the Law on Euthanasia of 28 May 2002.

3.2.4.5 Non-assistance to a person in danger

Pursuant to Article 422 bis of the Penal Code it is an offence to fail to come to the assistance, or to obtain assistance for a person in serious danger, when such danger is known directly or has been communicated by others who request such assistance.

The offence is constituted by the failure to provide assistance, whether or not the person dies as a result.

It cannot be excluded that the offence under Article 422 bis might technically be involved in certain acts of euthanasia carried out by a physician, in which case the “safe harbour” of the Law on Euthanasia of 28 May 2002 would be available, provided all the conditions laid down by that law were respected.

3.2.4.6 Murder and murder at the request of the victim

Murder, i.e. voluntary homicide, is a criminal offence under Article 393 of the Penal Code, and homicide with premeditation is a more serious offence, characterised as “assassinat” under Article 394 of the Penal Code. It is no defence to say that the victim requested to be killed.

On the other hand, there is a valid defence if the taking of life is carried out by a physician as an act of euthanasia in accordance with the strict terms of the Law on Euthanasia of 28 May 2002.

Conversely, an act of euthanasia which is carried out at the request of the victim without complying with the provisions of the Law on Euthanasia of 28 May 2002 can be considered as voluntary homicide or homicide with premeditation (assassinat) according to Articles 393 and 394 of the Penal Code.⁴

⁴ Les Avis de la C.N.E. – L'aide au suicide et l'euthanasie, Avis 1/98 de la Commission Consultative Nationale d'Ethique pour les sciences de la Vie et de la Santé (Ministère de l'éducation nationale et de la formation professionnelle – Luxembourg)

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3.3 Bulgaria

3.3.1 Consent

3.3.1.1 Consent to medical treatment

Article 87 of the Law of Health of 1 January 2005 (last amended 02.09.2009) states that medical activities may only be implemented after expressed informed consent has been given by the patient. Article 88 specifies the kind of information that the doctor should provide to the patient, which includes details of the diagnosis and the nature of the disease, details of the nature and goals of the treatment, possible alternatives, expected outcomes, potential risks, the likelihood of a favourable outcome and the risks involved in opting for an alternative treatment or in refusing treatment (Goffin et al., 2007).

3.3.1.2 Consent to treatment in the case of incapacity

In the case of incapacity, a few options for consent exist:

1. If the patient is "under limited interdict" (under partial legal incapacity) with regard to medical activities, his/her consent as well as that of his/her guardian is required (article 87 of the Law of Health).
2. If the patient is "judicially incapable" (under full legal incapacity) informed consent must be provided by the guardian (except in cases determined by law).
3. For patients with mental disorders and established inability to express informed consent, such consent shall be expressed by persons mentioned in article 162 of the same law.

Article 162, paragraph 3 of the Law of Health states:

"When a lack of ability of the person is accepted, the court shall decree compulsory treatment and appoint a person from the relatives of the ill person, who is to express informed consent for the treatment. Upon conflict of interests or lack of relatives, the court shall appoint a representative of the municipal health service or a person, defined by the mayor of the municipality at the headquarters of the medical establishment, who is to express informed consent about the treatment of the person."

In certain cases, this information and the informed consent must be given in writing. Such cases include surgical intervention, total anaesthesia, and invasive and other diagnostic and therapeutic methods leading to an increased risk to the life and health of the patient or to a temporary change in his/her consciousness.

Medical care can only be carried out without the necessary consent in specific cases determined by law (art. 91).

3.3.1.3 Consent in case of emergency

The medical activities mentioned earlier which necessitate written informed consent can be carried out without written informed consent only if the patient's life is immediately threatened and:

1. his/her physical or mental status does not allow the expression of informed consent;
2. it is impossible to obtain informed consent from the guardian or the trustee or by the person mentioned in art. 162, para 3.

For people with mental disorders and established inability to express informed consent, such medical activities can only be carried out with the permission of the commission for medical ethics and after obtaining the consent of lawful representatives or of the chief of the medical establishment (if there is no commission for medical ethics).

3.3.1.4 The right to refuse treatment

At any time, the patient, his/her guardian or trustee or his/her appointed representative can refuse proposed medical care or the continuation of medical activities. Such refusals must be signed and recorded in the patient's medical file. If those concerned are unable or refuse to sign, the treating doctor and a witness must sign in their place (art. 90).

If treatment is refused and this threatens the life of the patient, the chief of the medical establishment can decide to initiate life saving treatment.

3.3.1.5 The right to withdraw consent

As stated above, the patient, his/her guardian or trustee or his/her appointed representative can refuse the continuation of medical activities (i.e. withdraw consent that has already been given). The patient may also withdraw the refusal of treatment at any time. Medical care against the wishes of the patient may be given only in cases determined by law.

3.3.1.6 Consent to the donation of organs and/or human tissue

According to article 24 (1) of the Law on Transplantation of Organs, Tissues and cells, organs, tissues and cells may only be taken from living donors who have given written consent and provided that the removal would not endanger their lives. Before giving consent, potential donors must have been provided with understandable information about any risks involved (Goffin et al., 2007). Specific provisions relating to people with incapacity are not mentioned. In the case of incapacity, the consent to the donation of organs and human tissue has to be given according to the rules for patients under partial legal incapacity and under full legal incapacity.

3.3.1.7 Consent to clinical trials

The Act on the Medicinal Products in the Human Medicine states that a patient cannot be involved in a clinical trial until s/he has been informed beforehand by a doctor

(member of the research team) and provided with a full explanation of the goals, risks, inconveniences and procedure. The doctor must also have informed the patient of the right to refuse to take part and have reassured the patient that refusal would not result in negative consequences for him/her.

3.3.1.8 Consent to research

It is stated in article 29 of the Constitution of the Republic of Bulgaria that nobody may be subjected to medical, scientific or other experimentation without his/her voluntary written consent.

3.3.2 Advance directives

Advance directives do not have legal status in Bulgaria.

3.3.3 Access to information/diagnosis

3.3.3.1 The right to be informed

In order to enable people to give informed consent, the doctor in charge must inform the patient or his/her proxy decision makers in a timely manner and in the appropriate amount and form (art. 88) of the following:

1. the diagnosis and the nature of the disease;
2. description of the purposes and the nature of the treatment, the reasonable alternatives, the expected results and the prognosis;
3. the potential risks, connected with the proposed diagnostic – methods of treatment, including side effects and unwanted medical reactions, pain and other discomforts;
4. the probability of a favourable outcome, risks for the person's health of applying other methods of treatment or of refusal of treatment.

3.3.3.2 Access to medical files

According the last amendments of the Law of Health of 02.06.2009, article 28b, the patient has the right to receive from the hospital health information relating to his/her health, including copies of all medical documents.

Patients have the right to access medical records related to their health (article 86 of the Law of Health).

3.3.3.3 The right to designate another person to be informed on one's behalf

Article 92, paragraph 4, of the Law of Health gives patients the right to authorize in writing a person to be informed on their behalf of the above-mentioned information.

According to the new text of article 28b of the Law of Health the patient has the right to authorize in writing another person to examine his/her medical documents and make copies of them.

After the death of the patient his/her relatives have the right to inspect the health information, and to make copies of his/her medical documents.

3.3.3.4 The doctor's right to withhold information

There is no legal regulation of the therapeutic exception in Bulgarian law which means that doctors cannot withhold relevant information from patients (Goffin et al., 2007). According to Bulgarian law the doctor is obliged to tell the patient all information about the disease.

3.3.3.5 The patient's right to refuse information

A patient can refuse certain types of information. This includes information about the condition for which he/she has sought medical attention, as well as information about planned medical activities and related risks linked to that condition. Such refusal must be in writing (Article 92 (2-3) of the Law of Health).

3.3.3.6 Confidentiality/disclosure of information to other people

Article 86 states that patients have the right to the protection of data related to their health status. Health information may only be divulged to third parties in specific cases e.g. where the person is going to continue treatment elsewhere, where there is a danger to the health or life of other people or for statistical purposes once the data identifying the patient has been removed etc. (art. 28).

3.3.4 End-of-life care and issues

3.3.4.1 Palliative care

In the Law of the Treatment Institutions, 59 hospices are registered (of which 7 are not operational). There are no regulations governing the organisation and activities of hospices. There are also some homes for the elderly which provide palliative care (EAPC, 2006).

In the Law of Health of 1 January 2005 (art. 95 and art. 96), it is stated that patients with incurable diseases with unfavourable prognoses have the right to palliative medical care. The aim of such care is to maintain the patient's quality of life by the reduction or removal of certain consequences of the disease as well as any associated unfavourable psychological and social effects.

Palliative medical care should, according to article 96, include:

- medical observation;
- healthcare, aimed at caring for the patient, the removal of pain and the psycho-emotional effects of the disease;
- moral support of the patient and his/her relatives.

The requirements for palliative care are determined by an ordinance from the Minister of Health (art. 96).

3.3.4.2 Euthanasia

According to the European Association for Palliative Care (2006):

"At the current time, there are no initiatives in Bulgaria that seek the legalisation of euthanasia or assisted suicide. The Bulgarian Orthodox Church and Christian tradition do not allow life to be taken (even in the form of euthanasia). The problem is not discussed because both the medical community and society in general are not ready yet to discuss it."

The Republic of Bulgaria does not apply euthanasia (article 97 from the Law of Health).

3.3.4.3 Assisted suicide

Assisted suicide (either completed or attempted) is punishable by up to three years' imprisonment (art. 127). The sentence is more severe if the person who assisted another to commit suicide knew that he/she was unable to guide his/her acts or did not understand the gravity of the act. If a person leads another (who is dependant on him/her) to commit suicide as a result of cruel treatment or systematic humiliation, the punishment is imprisonment of two to eight years.

3.3.4.4 Non-assistance to a person in danger

According to the Penal Code, non-assistance to a person in danger is a criminal action.

Whoever puts in jeopardy a person who is unable to protect him/herself due to being a minor, superannuated, sick, or generally helpless, in such a way that his/her life could be in danger and, being aware of it, he/she does not come to his/her assistance, shall be punished by imprisonment of up to three years. (article137).

Whoever deliberately fails to render assistance to a person whom he/she is obliged to take care of and who is in danger of his/her life, and unable to protect him/herself for reasons of being minor, superannuated, sick, or generally helpless, in cases when he/she could have rendered assistance, shall be punished by imprisonment of up to one year or by corrective labour (art.138).

In the event of an immediate danger to somebody else's life arising, whoever does not come to their assistance, even though it could have been rendered without endangering themselves or somebody else, shall be punished by corrective labour for up to six months or by a fine of one hundred to three hundred levs. (art.139).

3.3.4.5 Homicide

Chapter 2 of the Penal Code (with amendments up to 23.06.2009) covers offences against the person.

Article 115 states that a person who deliberately kills somebody shall be punished for homicide by imprisonment for ten to twenty years. Article 116 lists cases/situations in which the definition "homicide" would apply. The killing of a person in a helpless state is included in the list. A person who helps someone else to commit homicide or causes the death of another person by negligence may be imprisoned for up to three years (art. 117 and art. 122).

3.4 Croatia

The Law on the Protection of the Rights of Patients by the Croatian Parliament was adopted on 19 November 2004 and came into force on 11 December 2004 (published in the Official Gazette No. 169/2004). It covers a variety of issues linked to consent and access to information, and will be referred to in this text as LPRP.

Prior to this law coming into force, the Croatian Association for the Promotion of Patients' Rights drafted a law proposal. As they have some criticisms of the existing law, the act they drafted, as well as a few articles about their concerns, can be found at: <http://www.pravapacijenata.hr/eng/>

3.4.1 Consent

3.4.1.1 Consent to medical treatment

Patients have the right to accept or refuse proposed medical treatment (including diagnostic and therapeutic procedures) unless such right has been restricted on the grounds of their condition (LPRP, art. 6-7). They can do this by stating their acceptance or refusal of the proposed treatment or by signing a consent form.

3.4.1.2 Consent to treatment in the case of incapacity

If a person has a severe mental disorder, does not have disposing capacity or is not of legal age to consent, the consent form must be signed by his/her legal representative or guardian (LRPR, art. 17).

3.4.1.3 Consent in case of emergency

A patient with full disposing capacity does not have the right to refuse urgent medical interventions if doing so would endanger his/her life and health, or cause him/her serious harm (LPRP, art. 16). For people with incapacity, the consent of the guardian or legal representative is not required if medical treatment or interventions are urgently needed (i.e. failure to provide treatment would directly and seriously threaten the patient's life or health) (art. 18).

3.4.1.4 Consent to clinical trials and research

Under the Healthcare Act of 1993, patients had the right to refuse to be observed, examined or treated by students and also the right to refuse to take part in scientific research. This act was replaced by the new Health Act of 2003 but the provisions relating to patients' rights remain almost identical.

In the Act on the Protection of Patients' Rights of 2004, it is stated that express consent must be given by patients, in written form, dated and signed, before they can participate in scientific research or be involved in medical teaching. Such consent must be made after the patient has been fully and precisely informed about the nature, risks and consequences of the research in a way that is understandable to him/her. The patient or his/

her legal representative or guardian may withdraw consent at any time (art. 19). Article 22 of the LRPR outlines certain conditions which must be fulfilled before people lacking capacity to consent can be involved in scientific research.

3.4.2 Access to information/diagnosis

3.4.2.1 The right to be informed

The right to be informed is part of the right to accept or refuse treatment as patients must have received the relevant information before giving or refusing consent. Information must include details about any risks and benefits of having or not having the proposed treatment, examinations or procedures as well as what would be involved, and this must be done in a way that is understandable and suited to their age, level of education and mental capacity. They must also be informed that they have the right to decide on the proposed treatment. Such information must be provided in a way that is in keeping with the patient's age, mental abilities and education (LRPR, art. 8).

Rusinovic and Proso (2005) draw attention to article 9 of the LRPR in which it is stated that the patient's right to be informed by the doctor is dependent on the patient's "spoken demand". This clearly discriminates against people who cannot make such a demand or who have difficulty communicating but who do not necessarily have a legal representative or guardian to ask on their behalf.

According to article 11, patients also have the right to be informed after each examination, procedure or surgery of its success or failure and of the possible reasons for results being different to those expected.

3.4.2.2 Access medical files

Patients are entitled to consult and copy (at their own cost) the parts of their medical files relating to their diagnosis and treatment (art. 23). This right extends to the marital or extramarital partner, adult children, parents, adult sisters and brothers and the guardian or legal representative of the patient upon the death of the latter unless he/she previously prohibited this in a statement made before a notary public (art. 24).

3.4.2.3 The right to designate another person to be informed on one's behalf

People can designate another person to receive health-related information on their behalf.

3.4.2.4 The patient's right to refuse information

Patients can refuse information about their condition and the expected outcome of treatment unless not knowing about the nature of their condition could result in them possibly endangering the health of other people (art. 14-15).

3.4.2.5 Confidentiality/disclosure of information to other people

Patients have the right to confidentiality of information linked to their health and to the protection of personal data. They may make a verbal or written statement indicating which people may be informed of their condition and of their hospitalization as well as those to whom such information should not be revealed (art. 25).

3.4.3 End-of-life care and issues

3.4.3.1 Assisted suicide

According to article 96 of the Criminal Code, whoever induces or assists another in committing suicide which is accomplished or attempted shall be punished by imprisonment for six months to five years. The sentence would be for one to eight years should the person's ability to understand or control his/her own will be significantly diminished. If such ability is totally lacking, the sentence would be the same as that for murder (i.e. not less than 5 years).

3.4.3.2 Non assistance to a person in danger

Whoever fails to render aid to a person in imminent mortal danger, although he/she could have done so without subjecting him/herself or another to serious danger, shall be punished by a fine or by imprisonment not exceeding one year. If the mortal danger was caused by the person in question, the punishment would be of a fine or imprisonment not exceeding three years (article 104 of the Criminal Code).

3.4.3.3 Deserting a Helpless Person

A person who deserts a helpless person in his/her trust, or for whom he/she is responsible, unassisted and in circumstances which represent a danger to the health or life of the former shall be punished by imprisonment of between three months and three years. Should such behaviour result in the death of the helpless person or serious bodily injury or serious impairment, the sentence shall be for one to five years' imprisonment (article 105 of the Criminal Code).

3.4.3.4 Murder at the request of the victim

Article 94 of the Criminal Code states that whoever kills another upon his/her express and earnest request shall be punished by imprisonment for one to eight years.

3.4.3.5 Murder

A person who kills another person is guilty of murder and may be punished by not less than five years' imprisonment (article 90 of the Criminal Code). In case of manslaughter (i.e. when the killing occurs on the spur of the moment in a state of strong irritation or fright brought on by another person's attack, maltreatment or serious insult), the punishment would be for one to ten years (article 92 of the Criminal Code). In case of death caused by negligence, the sentence would be from six months to five years (article 95).

3.4.4 Bibliography

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3.5 Cyprus

3.5.1 Consent

The following information is taken from Law No. 1 (I) 2005 Safeguarding and Protection of the Patients' Rights Law, which came into force on 7 April 2005 and can be downloaded at: [http://www.bioethics.gov.cy/Law/cnbc/cnbc.nsf/AII/6960B7A5AA76C4A3C22571C9002B99F0/\\$file/Patients%20Rights%20Law-English%20translation.pdf](http://www.bioethics.gov.cy/Law/cnbc/cnbc.nsf/AII/6960B7A5AA76C4A3C22571C9002B99F0/$file/Patients%20Rights%20Law-English%20translation.pdf)

3.5.1.1 Consent to medical treatment

Article 11 (1) states, "A prerequisite for the provision of healthcare is the patient's consent given after complete medical information, which is provided by the healthcare services provider to the patient, in due time, and in a manner that is comprehensible to the patient, so that the latter may understand the information provided and make a free and independent choice."

If the patient has chosen someone else to receive information on his/her behalf (please see relevant section), this person has the right to decide on his/her behalf. Such consent can be given in writing or orally, provided that it is put in writing as soon as possible.

In article 21 (4) of this Law, it is stated that in the case of patients who do not have the capacity to exercise their rights (which includes consent), such rights shall be exercised by a legal representative or a person whom the patient has appointed to that effect. If a representative is not available, reasonable measures must be taken in order to ensure the effective exercise of the patient's rights.

A person who has been appointed by law to consent on behalf of a patient must involve the latter in the decision-making process to the extent that his/her capacity and circumstances allow this.

3.5.1.2 Consent in case of emergency

In situations where medical care is urgently needed and the patient is in no position to express his/her will due to his/her mental or physical state, consent can be presumed, unless it is obvious from previously expressed wishes that he/she would have refused (article 13, § 1).

If someone has or should have been appointed by law to consent on behalf of a patient (due to the patient's mental or physical state) and such consent cannot be obtained in time, the consent of the patient for urgent medical care can be presumed, unless it is obvious that, in the circumstances, the patient would have refused (article 13, § 2). In such cases, the patient shall be involved in the decision-making process to the extent that his capacity and circumstances allow this.

If healthcare is urgently needed and proper consent cannot be obtained, article 13, § 5 authorizes healthcare service providers to provide such care provided that it is deemed to be in the patient's best interests or beneficial to his/her health. Previously expressed wishes should in such cases be taken into consideration.

3.5.1.3 Refusal of consent (by proxy decision maker)

If the person appointed to consent on behalf of the patient refuses to give such consent and the healthcare provider believes that the treatment is in the patient's best interests, he/she can, time permitting, refer to a court or other body prescribed by law. In the case of a medical emergency, the healthcare provider must act in the patient's best interests (article 13, § 4).

3.5.1.4 The right to refuse treatment

There does not seem to be any explicit reference to the refusal of consent in Law No. 1 (I) 2005 although the possibility of refusing treatment can be detected in a few articles. For example, article 11 (§ 1) states that consent is a prerequisite for the provision of healthcare so presumably healthcare cannot be provided if such consent is not given (i.e. if it is refused). Similarly, the obligation on the part of doctors to inform patients about the likelihood of success and the possible risks of various forms of treatment but also of non-treatment suggests the possibility of refusing consent (article 12, d). Finally, article 13 (1) makes a reference to the refusal of consent in previously expressed wishes.

3.5.1.5 Consent to non-conventional treatment

For innovative treatment, the patient (or his/her representative) must be appropriately informed. Written consent must be obtained (article 11, § 3).

3.5.1.6 Consent to participate in clinical teaching

The patient's consent must be obtained if he/she participates in clinical teaching (article 11, § 5).

3.5.1.7 Consent to the donation of organs and/or human tissue

Consent must be obtained from the patient to use any substances from his/her body. Such consent may be presumed if the substances are to be used for the purposes of diagnosis, treatment or care for which consent has already been obtained (article 11, § 4).

3.5.1.8 Consent to research

According to the provisions of article 14, § 1, people may take part in scientific research and experimental treatment if the following conditions are met:

- there is no alternative solution of comparable effectiveness;
- the risks which may be incurred by that patient are not disproportionate to the potential benefits of the research;

- the research project has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aim of the research and multi-disciplinary review of its ethical acceptability;
- the patient has been informed of his/her rights prescribed by this law.

The following additional conditions (article 14, § 2) apply just to people who are unable to consent:

- the results of the research have the potential to produce real and direct benefit to his/her health;
- research of comparable efficiency cannot be carried out on individuals capable of giving consent;
- the necessary authorization provided for in article 13 (covering healthcare without the consent of the patient) has been given specifically and in writing, and
- the person concerned does not object.

3.5.1.9 Consent to clinical trials

It is not clear whether the above conditions also apply to participation in clinical trials.

3.5.2 Advance directives

Information is missing about advance directives. However, there are two references in article 13 to previously expressed wishes:

13, § 1 Where the patient is in no position, due to his/her mental or physical state, to express his/her will and the provision of medical care is urgently needed, the consent of the patient may be presumed, unless it is obvious, from previously expressed wishes that he/she would have refused.

13, § 5 In any case where proper consent is impossible to be obtained

- a) any healthcare imposed as urgent may only be provided if the healthcare services provider deems it to be of benefit to the patient's health or in the patient's best interests;
- b) any previously expressed wishes of the patient concerning healthcare shall be taken into consideration.

Whenever healthcare is provided without the prior consent of the patient, any previously expressed wishes concerning healthcare must be taken into consideration. However, there are no guidelines as to how previously expressed wishes should be recorded, the extent to which they are binding or just advisory and whether they must be made in writing.

3.5.3 Access to information/diagnosis

Articles 10, 12, 13, 15 and 18 of Law No. 1 (I) 2005 Safeguarding and Protection of the Patients' Rights deal with access to information.

3.5.3.1 The right to be informed

Article 10 (§§ 1-6) states that every person has the right to be informed about patients' rights and to have sufficient information about health services, as well as ways to make better use of them. Patients are also entitled to complete medical information. Any information given to the patient or his/her selected representative (please see below) must be in a comprehensive form with as little as possible technical terminology. Medical information is defined in article 12 as:

- the diagnosis of the patient's medical condition and, if possible, its prognosis;
- a description of the purpose, anticipated benefit and likelihood of success of the proposed treatment;
- the risks entailed in the proposed treatment, including side-effects, pain and discomfort;
- the likelihood of success and the risks of various forms of treatment or non-treatment.

3.5.3.2 Access medical files

Article 18 of Law No. 1 (I) 2005 Safeguarding and Protection of the Patients' Rights covers access to medical records. It states that patients and their legal representatives have the right to access and if necessary rectify, erase or block records on the grounds that the information is inaccurate or missing. They are also entitled to receive a copy or extract of such information unless this information is likely to cause serious harm to the patient's health or, in the case of genetic data, to certain relatives, or would unavoidably lead to the disclosure of information about other people. These rights may be directly or indirectly exercised through a patient's legal representative.

Certain provisions of the Processing of Personal Data (Protection of Individuals) Laws of 2001 and 2003, as well as of the Processing of Personal Data (Licenses and Fees) Regulations of 2002 may also be relevant.

3.5.3.3 The right to designate another person to be informed on one's behalf

People have the right to appoint someone else to receive information on their behalf (article 10, § 5). If such a person is appointed, he/she also has the right to decide on behalf of the patient.

3.5.3.4 The doctor's right to withhold information

Article 10, § 3 states that certain information may exceptionally be withheld from the patient on the grounds that it might cause serious harm to his/her mental or physical

health. However, such information must be provided to the spouse, father, mother and descendants (whichever is reasonable in the circumstances) (article 11, § 1).

3.5.3.5 The patient's right to refuse information

The patient can refuse to receive information but such refusal is only valid if it is in writing. This right can be deduced from article 10, § 4 which states, "The patient is not considered to have disclaimed the right to information, unless he/she has so requested in writing." According to article 10, § 5, the patient also has the right to choose another person to be informed on his/her behalf.

3.5.3.6 Confidentiality/disclosure of information to other people

Article 15 of Law No. 1(I) 2005 Safeguarding and Protection of the Patients' Rights covers confidentiality. Paragraph 1 contains the following provisions:

- a. Subject to the provisions of subsection (2), all information about the patient's medical condition, diagnosis, prognosis and treatment, as well as any other personal data shall be kept confidential even after the death of the patient and shall not be disclosed to any person or authority.
- b. The competent healthcare service provider or any person working in a medical institution shall not disclose any information regarding a patient which comes to his knowledge in the course of his duties or his/her work.
- c. The administration of a medical institution or the competent healthcare service provider shall make the necessary arrangements to ensure that persons working under their direction shall not disclose such information.

The provisions of subsection 2 (mentioned above) permit the disclosure of medical information to other people in certain circumstances, e.g. if the patient has given written consent to do so or if non-disclosure is likely to lead to serious harm to other people or society as a whole. Consent to disclose information can also be presumed where such disclosure is necessary for the treatment of the patient.

In cases where information about a patient is disclosed, the patient's identity must be protected and the people receiving the information are to keep such information confidential.

The right to privacy is covered in article 15 of the Constitution of Cyprus which states, "Every person has the right to respect for his private and family life".

3.5.4 End-of-life care and issues

3.5.4.1 Palliative/end-of-life care

Law No. 1 (I) 2005 Safeguarding and Protection of the Patients' Rights contains a section on dignified treatment. Article 5, § 4 of this act states that patients have the right to

healthcare and respect of their dignity all through the final stage of their lives, within the limits of the law and legitimate procedures.

Additional rights covered in this section of the law (but not necessarily limited to end-of-life care) include the following:

- the right to be treated with dignity during healthcare provision, which shall be rendered with appropriate respect for the person's cultural values;
- the right to enjoy the support of one's family, relatives and friends and continuous spiritual support, including religious as well as psychological support and guidance, if needed (.../...);
- the right to be relieved from pain and suffering, in accordance with the available scientific knowledge and the Medical Professional Ethics Regulations of the Board of the Pancyprian Medical Association, in force for the time being, within the limits of the law and legitimate procedures.

3.5.4.2 Euthanasia/assisted suicide

Article 218 of the Criminal Code (amendment) Law 46/1982 prohibits assisted suicide (Council of Europe, 2003).

Although there is no legislation on euthanasia, doctors who carry out euthanasia may face disciplinary proceedings according to codes of medical deontology (Council of Europe, 2003).

According to the European Association for Palliative Care (2006), there are no initiatives in Cyprus seeking the legalisation of euthanasia or assisted suicide.

3.5.5 Bibliography

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3.6 Czech Republic

3.6.1 Consent

The following information on consent and information is based on the Healthcare Act No. 20 of 1966 (and subsequent amendments). As we had no access to this law, the information in the following two sub-sections is taken from a report on patients' rights produced by Nys et al. (2006).

In addition, issues related to consent and the provision of information are also covered by the provisions of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Haškovcová, 2002). This is because the Convention became part of Czech legislation after it was signed and ratified by the Czech Parliament. However, the general public is largely unaware of this.

3.6.1.1 Consent to medical treatment

According to article 23, section 2, of the Healthcare Act No. 20 of 1966, examinations and treatments are provided with the consent of the patient or if such consent can be presumed. In the case of adults lacking legal capacity, who have a legal representative, presumably that legal representative would be able to consent on their behalf as article 26 of the Civil Code states that if individuals are not capable of legal acts, they shall be represented by their legal representatives.

More recently, Regulation No. 385/2006 states that healthcare institutions must provide documentation about healthcare provision and obtain informed consent.

People with dementia who do not have the capacity to give informed consent but are not actually legally capacitated are not adequately protected. They may sign a consent form without having fully understood what they are agreeing to (Holmerová et al., 2008).

3.6.1.2 Consent in case of emergency

Treatment can be provided without the prior consent of the patient if the patient shows signs of a mental illness and is a danger to him/herself or to his/her surroundings or if it is not possible, given the state of health of the patient, to obtain his/her consent and urgent medical treatment is necessary (article 23, section 4).

3.6.1.3 The right to refuse treatment

A person who refuses a medical intervention, despite having received the necessary information, must give written confirmation of this refusal (Healthcare Act No. 20 of 1966, § 23, subparagraph section 2).

If the curator of a person lacking the legal capacity to act refuses to consent to treatment that is necessary to save that person's life, the doctor can (according to § 23, subsection 3) decide whether or not to provide treatment. However, it seems that this provision is limited to people lacking legal capacity and for whom a curator has been appointed. The provisions for a person who lacks capacity but has not been declared legally incapacitated by a court of law are unclear (Nys et al. 2006).

Regulation No. 385/2006 Sb. also covers the refusal of healthcare but again, this only applies to people with capacity (Holmerová et al., 2008).

3.6.1.4 Consent to research

Written consent must be given by the patient before scientific research can be carried out on him/her. Before giving consent, the patient must have been informed about the nature and purpose of the research, how it will be carried out, how long it will take and whether there are any risks involved (article 27b).

3.6.2 Advance directives

There is no legislative framework for advance directives in the Czech Republic.

3.6.3 Access to information/diagnosis

3.6.3.1 The right to be informed

Doctors must inform patients in an appropriate manner about the nature of their illness and about any necessary medical procedures so that patients can play an active role in the provision of their medical care (article 23, subsection 1). In the case of incapacitated adults, members of the family should be informed.

3.6.3.2 Access to medical files

On 20 December 2006, the Hradec Králové Regional Court confirmed that patients in the Czech Republic are entitled to see their medical records and to consult independent experts on their contents. A person cannot be denied this right solely on the basis of a psychiatric diagnosis (Source: Mental Health Europe, 2007).

3.6.3.3 The doctor's right to withhold information

The right to withhold information about a patient's health is not covered by law but is mentioned in the Code of the Czech Medical Chamber as being possible if the diagnosis or prognosis is unfavourable and it would be in the patient's interests not to be informed. However, this does not have any legal power (Nys et al., 2006).

3.6.3.4 The patient's right to refuse information

A patient may refuse information on his/her health status.

3.6.3.5 Confidentiality/disclosure of information to other people

Article 55 of the Healthcare Act of 1966 deals with the obligation of medical professionals to maintain confidentiality with regard to information about the patient obtained in the exercise of their occupation.

3.6.4 End-of-life care and issues

3.6.4.1 Euthanasia/assisted suicide

The following extracts are taken from a report by the steering committee on bioethics (Council of Europe, 2003):

"The term "assisted suicide" is clearly defined by current Czech legislation as intentionally assisting a person to terminate his or her life at his or her request and according to Czech Penal Law, it is considered to be a crime with possible criminal sanction of imprisonment for a duration of 6 months to 3 years.

The Ethical Code of The Czech Medical Chamber (professional organisation representing all physicians practising in Czech Republic) from 1.1.1996 declares euthanasia and assisted suicide to be unacceptable. Nevertheless it emphasises that the relevant goal of care in a terminally ill and dying patient is the relief of physical symptoms and of suffering and not only the prolongation of life."

Euthanasia is an intentional criminal delict according to the penal code. However, if the court decides that the penal sanction is too severe, it may consider that the purpose could be achieved by a less severe sanction it may decide for sanction under the threshold given by the law. However the minimum is 3 years.

3.6.4.2 Non-assistance to a person in danger

It is a criminal act according to the penal code not to provide necessary assistance to a person in severe danger to life or health and is subject to a penal sanction up to one year (for health or social care professionals up to 2 years and/or prohibition to exercise their profession).

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3.7 Denmark

Part 3 of the consolidating Act of Health (No. 95) of 7 February 2008⁵ includes a clause which states that the patient's dignity, integrity and right of self determination must be respected. This reflects the approach to decision making in the healthcare context.

3.7.1 Consent

3.7.1.1 Consent to medical treatment

Part 3 of the consolidating Act of Health contains the rules about Patients' Legal Status (No. 95) of 7 February 2008 stipulates that no treatment may be initiated or continued without the informed consent of the patient. This is not limited to patients being treated in a hospital but covers patients who are receiving or have received treatment in any place where healthcare is carried out. Treatment is to be understood as meaning examination, diagnosis, treatment of illness, professional healthcare or preventive measures. For consent to be valid, it can be given in writing, verbally or according to the circumstances but it must be based on the patient having been provided with the necessary information from the healthcare provider. Once given, consent can be withdrawn at any time.

However, in the case of dementia, the patient may be unable to give informed consent. § 18 of the law stipulates that the closest relatives of a patient, who permanently lacks the ability to give informed consent, can give it on his/her behalf. If the patient is under guardianship, the guardian can give consent on his/her behalf. The law states that the person who cannot give informed consent must be informed and involved in the deliberations to the extent that he/she can understand and that this would not cause injury. This includes taking into account the person's views if they are current and relevant.

For those who do not have relatives or a guardian, the healthcarer can provide the necessary treatment provided that another independent healthcarer gives approval. If the treatment is of a minor nature, approval is not necessary. Section 4 of § 18 envisages the case where a relative or guardian might use the power to consent in a way which could result in injury to the patient or which might jeopardise the treatment. If the health provider feels that this is the case, he/she can proceed with the treatment, provided that approval is obtained from the relevant official medical institution.

3.7.1.2 Consent in case of emergency

In the case of emergency treatment, a person who is temporarily or permanently unable to consent can be treated even in the absence of authorisation from relatives or guardians.

3.7.1.3 Consent to clinical trials

According to § 12 of Act No. 402 of 2003 on Scientific Ethical Committee System and Treatment of Biomedical Research Projects, a person with impaired capacity can take

⁵ Bekendtgørelse af Sundhedsloven nr. 95 af 7. febr. 2008

part in biomedical trials with informed consent from the closest relatives and the general practitioner, alternatively the medical officer of health or a guardian with competence to give consent in these situations as stated in § 5 of the Guardianship Act of 2007.

3.7.2 Advance directives

3.7.2.1 The legal status of advance directives

Advance directives have legal status in Denmark according to the consolidated Act of Health (No. 95, 2008). They are legally binding in certain circumstances and advisory in others. Some people express their future wishes in powers of attorney documents. Such wishes are not legally binding but may serve as guidelines for the attorneys who have been appointed.

3.7.2.2 Conditions surrounding the writing, validity and registration of an advance directive

Any person over the age of 18 who is not already under guardianship can write an advance directive. Capacity is presumed. It is not necessary to involve a doctor or notary. There is a registration procedure in that advance directives must be sent to a Central Registry. The registration procedure currently costs about Euro 7. The validity of advance directives is not limited to a set period of time.

3.7.2.3 What an advance directive can cover

Such a will may specify:

- 1 That life prolonging treatment would not be desired if the testator were facing unavoidable death;
- 2 That life prolonging treatment would not be desired in case of illness, advanced debilitation due to old age, accidents, heart failure or similar situations that cause such a severe invalidity that the testator would be permanently unable to take care of him/herself physically and mentally.

Life prolonging treatment is described as meaning treatment where there is no outlook for cure, improvement or alleviation but only to a certain prolongation of life. If a health professional is considering giving life prolonging treatment to a person who is unable to consent, he/she must consult the Will Registry to check whether the person has made one. Wishes in line with number 1 above are legally binding and must therefore be respected whereas wishes in line with number 2 above are merely advisory but must be registered in the medical notes.

3.7.2.4 Obligation to comply with instructions contained in an advance directive

A person may specify in an advance directive that life-supporting treatment is not desired should they be facing unavoidable death i.e. where there is no outlook for cure, improvement or alleviation but only to a certain prolongation of life. In such cases, doc-

tors must consult the Will Registry to check whether the patient has made an advance directive. If so, it is considered as legally binding.

A person may also or alternatively specify in an advance directive that life-supporting treatment is not desired in case of illness, advanced debilitation due to old age, accidents, heart failure or similar situations that cause such a severe invalidity that they would be permanently unable to take care of themselves physically and mentally. In such cases, doctors must again consult the Will Registry to check whether the patient has made an advance directive. If so, it is considered as advisory.

If a person expresses wishes just before losing capacity which differ from those contained in the advance directive, doctors normally take these wishes into account.

3.7.2.5 Amending, renewing and cancellation of advance directives

An advance directive can be amended or cancelled at any time simply by informing the Will Registry. This can be done by a person with and presumably without capacity (provided that they have sufficient capacity to be able to inform the Will Registry).

3.7.3 Access to information/diagnosis

3.7.3.1 The right to be informed

Part 3 of the consolidating Act of Health contains the rules about Patients' Legal Status (No. 95) of 7 February 2008. Patients have the right to receive information on their state of health and on different possibilities for treatment including the risk of complications and side effects. This should therefore include the obligation to inform the person of his/her diagnosis. He/she should also be given information on relevant preventative treatment and on the kind of care that can be provided. The consequences of not implementing a particular form of treatment should also be given to the patient and if a patient is unaware of certain facts which are considered to be important in order to make a decision, the medical professional should provide this information.

3.7.3.2 Access to medical files

Chapter 8 of the consolidating Act of Health (No. 95) of 7 February 2008 covers the right of access to patient case records. This includes records kept in hospitals, clinics, outpatient clinic, in private practice or in connection with treatment received at home. If a person wants to gain access to such information he/she submits a request to the relevant person or authority who is obliged to provide an easily understandable report which should include:

- The information which is being kept;
- The purpose of the treatment;
- Who has access to such information;
- Where the information came from.

The relevant authority, institution or health professional who has the patient's record determines whether he/she will be granted access to it. Access can be limited or denied if it is considered that it would be in the best interests of the patient to do so, or in order to protect the private interests of others.

3.7.3.3 The doctor's right to withhold information

Regarding the right of access to patient case records (mentioned above), access can be limited or denied if it is considered that it would be in the best interests of the patient to do so, or in order to protect the private interests of others.

3.7.3.4 The patient's right to refuse information

If a patient does not want this or other information relating to treatment, he/she can refuse it. On the contrary, if such information is required, it is the duty of medical professionals to explain what an illness involves, the examination and treatment being considered in a considerate manner and one which is adapted to the individual's age, maturity and experience, etc.

3.7.3.5 Confidentiality/disclosure of information to other people

§ 40 of the consolidating Act of Health (No. 95) of 7 February 2008 grants the patient the right to confidentiality from a healthcarer during the performance of his/her duty with regard to health conditions, strictly private situations and other confidential information. Medical secrecy is also covered in the Practice of Medicine Act. However, information can be disseminated to others with and without the person's consent under certain conditions.

Nevertheless, if a person, such as a health professional or researcher, wrongfully disseminates confidential information about a person's health or other related information, he/she would be liable for punishment according to §§ 152-152f of the Penal Code.

Information relating to the patient's state of health, strictly private conditions and other confidential information linked to treatment can be disseminated to other healthcarers, provided that the patient has consented to this. The same information can be disseminated without the patient's consent if it is necessary for the progression of a treatment or for the justified care of the patient and if this corresponds with his/her interests and needs. Such information can also be passed on to a substitute doctor (according to § 41 of the consolidating Act of Health, No. 95 of 7 February 2008).

Healthcarers can give the above mentioned information to authorities, organisations, private persons and others if the patient has consented to this, but can also provide such information without having consent if this is considered necessary in the public interest or as a result of significant concern to the patient, the healthcarer or others (§ 43).

Information about the illness as well as the cause and manner of death of a patient can be given to the nearest relatives of the deceased, provided that it may be assumed that

this would not be contrary to his/her wishes. However it can be given without consent if it is judged to be necessary to others (§ 45).

According to § 14, for the purposes of the consolidating Act of Health, No. 95 of 7 February 2008, if the patient is unable to take care of his/her interests, the person or people who are legally authorised to act on his/her behalf can intervene to the extent necessary to protect the patient's interests. This means that in instances which refer to consent to the dissemination of or access to information, a near relative or a guardian is allowed to consent to such dissemination or access on behalf of a person with dementia.

3.7.3.6 Dissemination of health information for special purposes

Information on an individual's state of health and other personal information from a patient's case records can be revealed to researchers for the purpose of biomedical research. Permission for the project must have been obtained in accordance with the Danish Act (No. 402 of 2003) on a Scientific Ethical Committee System and Treatment of Biomedical Research Projects (and subsequent amendments). If not covered by this law, researchers engaged in research projects of significant social interest may still be granted access to information on the approval of the National Health Service.

Once personal and health information has been obtained in this way, it cannot be used for anything other than statistical or scientific purposes. If results of the research are published, it must be done in a way, which makes it impossible to trace the information to particular individuals.

3.7.4 Euthanasia/assisted suicide

3.7.4.1 Palliative care (and the issue of double effect)

§ 25 of the consolidating Act of Health, No. 95 of 7 February 2008 also allows for the use of certain palliative treatments, which can have the side effect of accelerating death. The law states that "a fatally ill patient can receive the pain killing, tranquillising or similar means necessary to alleviate the patient's condition, even though this can lead to an acceleration of the time of death." This is known as the "double effect" and is only legal if the acceleration of death comes about as a side effect. The treatment must not be initiated or maintained with the sole purpose of shortening the patient's life. Furthermore, the doctor must treat each patient on an individual basis as opposed to increasing the dose automatically. For patients who are unable to consent, the decision for such palliative treatment is made by the doctor, but preferences could also be included in the advance directive.

3.7.4.2 Special leave to care for a terminally ill person

According to chapter 23 of the Consolidation Act on Social Services, carers are entitled to paid time off work to care for a terminally ill person who wishes to die at home and for whom hospital care is not needed. A special allowance may be allocated in the case of carers who are not in paid employment (Jensen, 2007).

3.7.4.3 Euthanasia

Passive euthanasia was incorporated into Danish law in 1992. In 1998 the section on advance directives was incorporated into the Law on Patients' Legal Status, now the consolidating Act of Health (No. 95) of 7 February 2008. The patient's right to decline treatment which merely serves to prolong life without offering any possibility of cure is in effect a form of passive euthanasia in that the doctor must in principle desist from pursuing it. Please refer to the section on advance directives for further details.

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3.8 Estonia

3.8.1 Consent

3.8.1.1 Consent to treatment

Paragraph 759 of the Law of Obligations Act of 26 September 2001 (hereafter referred to as LOA) states that the provision of healthcare services is based on a contract between the patient and the healthcare professional. This contract is deemed to have been entered into:

- upon commencement of the provision of healthcare services or assumption of the obligation to provide healthcare services with the consent of a patient;
- if commencement of the provision of healthcare services to a patient without the capacity to exercise his or her will corresponds to his or her actual or presumed intention.

According to § 766 of the LOA, a patient may be examined and healthcare services provided only with his or her consent. Such consent may be withdrawn within a reasonable period of time after having granted it. The provider of healthcare services may ask for such consent or an application to withdraw such consent in writing.

3.8.1.2 Consent for people with restricted active legal capacity

For patients with restricted active legal capacity, their legal representatives can act on their behalf insofar as they themselves are unable to consider the pros and cons responsibly. If it seems that the decision of a legal representative is not in the interests of a patient, the provider of healthcare services is not obliged to comply with the decision.

3.8.1.3 Consent for people with incapacity to express their will

§ 767 of the LOA covers the provision of healthcare services to patients without capacity to exercise their will and for whom a legal representative cannot be reached. It also states the necessity to consider previously expressed wishes and presumed intentions. No direct reference is made to advance directives. The text is as follows:

- (1) If a patient is unconscious or incapable of exercising his or her will for any other reason (a patient without the capacity to exercise his or her will) and if he or she does not have a legal representative or his or her legal representative cannot be reached, the provision of healthcare services is permitted without the consent of the patient if this is in the interests of the patient and corresponds to the intentions expressed by him or her earlier or to his or her presumed intentions and if failure to provide healthcare services promptly would put the life of the patient at risk or significantly damage his or her health. The intentions expressed earlier by a patient or his or her presumed intentions shall, if possible, be ascertained using the help of his or her immediate family. The immediate family of the patient shall be informed of his or her state of health, the provision of healthcare services and the associated risks if this is possible in the circumstances.

- (2) Within the meaning of this Chapter, immediate family means the spouse, parents, children, sisters and brothers of the patient. Other persons who are close to the patient may also be deemed to be immediate family if this can be concluded from the way of life of the patient.

3.8.1.4 The right to withdraw consent

Patients have the right to withdraw consent within a reasonable period of time after having given it (§ 766, 3, LOA). The doctor has the right to request that this be provided in written form.

3.8.1.5 Consent to non-conventional treatment

Paragraph 763 addresses the issue of non-conventional methods of treatment. A method of prevention, diagnosis or treatment which is not generally recognised may be used only if conventional methods are not likely to be as effective, if the patient is informed of the nature and possible consequences of the method and if the patient has granted his or her consent to the use of the method.

Consent to such treatment may be given by the legal representative of a patient with restricted active legal capacity. A generally unrecognised method may be used in respect of a patient without the capacity to exercise his or her will without the consent of the patient or his or her legal representative if failure to use the method would put the life of the patient at risk or would significantly damage his or her health.

3.8.1.6 Consent to the donation of organs and/or human tissue

The Transplantation of Organs and Tissue Act of 30 January 2002 establishes the conditions and procedure for the transplantation and removal of organs and tissue of human origin. People with limited legal capacity may not normally be donors. The conditions which allow them to donate organs or tissue are:

1. Regenerative tissue is transplanted.
2. There is no compatible donor available who has active legal capacity.
3. The recipient is a brother or sister of the donor.
4. Consent of the legal representative and permission of an administrative court judge for transplantation has been obtained.
5. The potential donor concerned does not object to transplantation. (Chapter 2, 2, 1-5).

3.8.1.7 Consent to research

Paragraph 138 of the Penal Code deals with the illegal conduct of human research. It states that the conduct of medical or scientific research on a person who has not granted consent thereto, pursuant to the procedure prescribed by law, or who before granting such consent was not notified of the essential potential dangers arising from the research, is punishable by a fine or up to 3 years' imprisonment. The same act, if committed by a legal person, is punishable by a fine.

3.8.1.8 Consent to the donation of genes

The Human Genes Research Act of 13 December 2000 contains a paragraph on the consent of people with restricted active legal capacity to become gene donors. Paragraph 20 states that their consent is deemed valid provided that the person with restricted active legal capacity and his/her legal representative or guardian have been given the information (described in the law); that the guardian or legal representative has given consent and that the person is not opposed to providing a tissue sample or to the collection of information about his/her state of health.

3.8.2 Advance directive

According to Antis Nömpere (Alzheimer Europe, 2006), advance directives are legally binding by virtue of article 767 of the Law of Obligations (mentioned earlier). Doctors cannot be obliged to provide treatment that is not in the best interest of the patient but can be obliged to discontinue treatment.

3.8.3 Access to information/diagnosis

3.8.3.1 The right to be informed

Informed consent is dependent on the patient having received the necessary information to make an informed decision. The following extracts are taken from the Law of Obligations Act of 26 September 2001 (§ 766):

- (1) The provider of healthcare services shall inform the patient of the results of examination of the patient, the state of his or her health, any possible illnesses and the development thereof, the nature and purpose of the healthcare services provided, the risks and consequences associated with the provision of such healthcare services and of other available and necessary healthcare services. At the request of the patient, the provider of healthcare services shall submit the specified information in a format which can be reproduced in writing.
- (4) In the case of a patient with restricted active legal capacity, the legal representative of the patient has the rights specified in subsections (1) (.../...) insofar as the patient is unable to consider the pros and cons responsibly. If the decision of the legal representative appears to damage the interests of the patient, the provider of healthcare services shall not comply with the decision. The patient shall be informed of the circumstances and information specified in subsection (1) of this section to a reasonable extent.

3.8.3.2 Access to medical files

Article 769 of the Law of Obligations grants patients the right to access their medical files and to obtain copies at their own expense (unless otherwise provided by law).

3.8.3.3 The doctor's right to withhold information

There is no law covering the therapeutic exception in Estonia (Nys et al., 2007).

3.8.3.4 The patient's right to refuse information

A patient has the right to refuse the above-mentioned information and the healthcare provider must respect this decision provided that the legitimate interests of the patient or other people are not damaged by this non-disclosure (§ 766).

3.8.3.5 Confidentiality/disclosure of information to other people

Paragraph 157 of the Penal Code covers the violation of the obligation to maintain confidentiality of secrets which have become known in the course of professional activities. This paragraph states that the disclosure of information obtained in the course of professional activities and relating to the health, private life or commercial activities of another person by a person who is required by law to maintain the confidentiality of such information is punishable by a fine.

3.8.4 End-of-life care and issues

3.8.4.1 Euthanasia/assisted suicide

It is stated in a report by the steering committee on bioethics (Council of Europe, 2003) that neither suicide nor assisted suicide is punishable in Estonia.

According to the European Association for Palliative Care (2006), there are no initiatives in Estonia seeking the legalisation of euthanasia or assisted suicide.

3.8.4.2 Non-assistance to a person in danger

Non-assistance to a person in danger is covered by paragraph 124 of the Penal Code:

§ 124 Refusal to provide assistance

Knowing refusal to provide assistance to a person who is in a life-threatening situation due to an accident or general danger, although such assistance could be provided without endangering the person providing assistance, is punishable by a fine or up to 3 years' imprisonment.

3.8.4.3 Manslaughter and negligent homicide

Whilst there is no direct reference in the Penal Code to euthanasia or assisted suicide, the following paragraphs might nevertheless be relevant:

§ 113 Manslaughter

Manslaughter is punishable by 6 to 15 years' imprisonment.

§ 117 Negligent homicide

Killing another person through negligence is punishable by up to 3 years' imprisonment.

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3.9 Finland

3.9.1 Consent

3.9.1.1 Consent to medical treatment

Consent to treatment is covered by section 6 of the Act on the Status and Rights of Patients, No. 785 of 17 August 1992. According to this Act, patients must be cared for on the basis of a mutual understanding, which means that they must consent to treatment. If they refuse a particular treatment, the doctor must propose another medically acceptable alternative to which they are in agreement. In certain circumstances, a person can be treated against his/her will.

Concerning patients who are unable to consent, section 6.2 and 6.3 of the Act on the Status and Rights of Patients states:

"If a major patient because of mental disturbance or mental retardation or for other reason cannot decide on the treatment given to him/her, the legal representative or a family member or other person closely connected to the patient has to be heard before making an important decision concerning treatment to assess what kind of treatment would be in accordance with the patient's will. If this matter cannot be assessed, the patient has to be given a treatment that can be considered to be in accordance with his/her personal interests."

"In cases referred to in paragraph 2, the patient's legal representative, a close relative, or other person closely connected with the patient, must give their consent to the treatment. In giving their consent, the patient's legal representative, close relative, or other person closely connected with the patient must respect the patient's previously expressed wishes or, if no wishes had been expressed, the patient's well-being. If the patient's legal representative, close relative, or other person closely connected with the patient forbid the care or treatment of the patient, care or treatment must, as far as possible in agreement with the person who refused consent, be given in some other medically acceptable manner. If the patient's legal representative, close relative or other person closely connected with the patient disagree on the care or treatment to be given, the patient shall be cared for or treated in accordance with his or her best interests." (9.4.1999/489)

However, a person/persons who make a decision on behalf of a patient cannot forbid treatment which is necessary to ward off a threat to the life or health of the patient (section 9).

3.9.1.2 Consent in case of emergency

Section 8 of the Act on the Status and Rights of Patients deals with emergency treatment. It states:

"A patient has to be given treatment necessary to ward off a hazard imperilling his/her life or health even in cases where it is not possible to assess the patient's will because of unconsciousness or other reason.

However, if the patient has earlier steadfastly and competently expressed his/her will concerning treatment given to him/her, he/she must not be given treatment that is against his/her will."

3.9.1.3 The right to refuse treatment

A competent patient has the right to refuse treatment. According to the Act on the Status and Rights of Patients (section 6.1), if a patient refuses a particular treatment, the doctor must propose another medically acceptable alternative to which they are in agreement.

Healthcare proxies also have the right to refuse treatment on behalf of an incompetent patient. According to section 6.3 of the Act on the Status and Rights of Patients, if the patient's legal representative, close relative, or other person closely connected with the patient forbid the care or treatment of the patient, care or treatment must, as far as possible in agreement with the person who refused consent, be given in some other medically acceptable manner. However, section 9 stipulates that healthcare proxies cannot forbid treatment which is necessary to ward off a threat to the life or health of the patient.

3.9.1.4 The right to withdraw consent

Competent patients have the right to withdraw consent.

3.9.1.5 Consent to non-conventional treatment

Competent patients have the right to give consent to non-conventional treatment.

3.9.1.6 Consent to the donation of organs and/or human tissue

It is possible for patients to consent to the donation of organs and human tissue through advance directives. Healthcare proxies can give such consent after the death of the patient.

3.9.1.7 Consent to research

Act No. 488 on Medical Research came into force on 1 November 1999. In this act, medical research is defined as being research which interferes with the integrity of a human being or a human embryo or foetus and whose intention is to increase knowledge of the cause, symptoms, diagnosis, treatment or prevention of the disease or its nature in general.

Paragraph 7 deals with consent from disabled subjects. This includes people who are unable to give their consent due to a mental health disorder, mental handicap or other equivalent reason.

Research can only be carried out on such people if the same scientific results could not be attained using other subjects and provided that the risk of causing damage or stress

is limited. Furthermore, research can only be carried out if it could be expected to be directly beneficial to the participant or to other people either of the same age or with the same medical condition. Even if these conditions have been fulfilled, the participant's legal representative, close relative, or other person closely connected with the patient must give written consent after having received the necessary relevant information. The consent has to be given in accordance to the presumed will of a participant. The provisions of article 6 also apply in that consent can be withdrawn at any time before completion of the research. Finally, if the participant objects to any procedure used as part of the research, he or she must not be forced to undergo the procedure.

3.9.2 Advance directives and healthcare proxies

3.9.2.1 The legal status of advance directives

Advance directives have legal status in Finland according to section 8 of the Act on the Status and Rights of Patients (No. 785/92 of 17 August 1992).

Section 8 of the Act on the Status and Rights of Patients deals with emergency treatment. A situation could arise whereby a patient, who is in need of emergency treatment, is unconscious or unable to express his/her will. According to section 8, doctors cannot give a treatment that is against his/her will, as expressed steadfastly and competently at some point in the past. In the sense that this section refers to the necessity to respect the previously expressed wishes of a person who is no longer able to state his/her preference regarding treatment, this can be considered as legitimising a kind of advance directive.

Paragraph 6.3 of the Act on the Status and Rights of Patients can also be interpreted as involving the possible use of advance directives in substitute decision making with regard to care⁶.

There are three categories of people who can decide on behalf of a person with incapacity:

1. the legal representative who could be either a guardian who is entitled to represent his/her client in issues linked to the client's person or a person appointed by the patient such as a power of attorney or continuing power of attorney in healthcare issues,
2. a family member; or
3. another person who is closely connected to the patient.

These people are not placed in any order of priority. However, the Ministry of Social Affairs and Health has plans to alter the Act on the Status and Rights of Patients in such a way that there would be a priority list of the proxy decision makers. After the alteration the possible legal representative would have priority to make decisions.

⁶ Please refer to the section on consent.

3.9.2.2 Conditions surrounding the writing, validity and registering of an advance directive

A person must have sufficient capacity to make a valid advance directive. Competence is presumed unless proven otherwise. In case of doubt, a doctor should assess a person's capacity.

There is no set procedure for writing or registering advance directives but they should be recorded in the patient's medical file. An advance directive can be made orally (e.g. by a person in hospital) or in writing. If made in writing, it is advisable to have two witnesses. A doctor and/or lawyer may be involved in the process of making an advance directive but this is not necessary.

Advance directives are not limited to a set period of time.

There is a new decree from the Ministry of Social Affairs and Health on Medical Files (30.3.2009/298). Paragraph 18.4 of the Decree on Medical Files states that if a patient wishes to express (orally) his/her steadfast will regarding future medical treatment, it should be recorded clearly, along with his/her signature, in the medical files. It is also possible to attach a separate advance directive to the medical files.

3.9.2.3 What an advance directive can cover

The Act on the Status and Rights of Patients states that in emergency situations "doctors cannot give a treatment that is against the will of a patient, as expressed steadfastly and competently at some point in the past".

In literature on jurisprudence it is interpreted that an advance directive can cover at least the following:

- The treatment of medical conditions;
- Care and welfare decisions;
- Research;
- Life-supporting treatment;
- Life-saving treatment; and
- The appointment of a healthcare proxy.

Nowadays, in practice, there are also so-called positive advance directives. These documents can express many kinds of wishes, e.g. what kind of food and drink the person likes, what their favourite clothing is etc.

3.9.2.4 Obligation to comply with instructions contained in an advance directive

In the case of emergency treatment, advance directives are legally binding. In literature on jurisprudence it is interpreted that they are legally binding in other cases too. At least it is good medical practice to comply with them.

The Ministry of Social Affairs and Health has plans to alter the Act on the Status and Rights of Patients. After the alteration, doctors will not be obliged to comply with advance directives if it is obvious that the advance directive is based on a person's false perception of their health condition, the nature of the illness or the effectiveness of the treatment methods and medication proposed. Similarly, doctors should not comply with an advance directive if the patient's will concerning treatment and care has changed for the above-mentioned or a similar reason.

If it would be against a doctor's personal beliefs to comply with instructions contained in an advance directive, the doctor must find a colleague who is willing to take over the treatment of the patient.

3.9.2.5 Amending, renewing and cancelling advance directives

An advance directive can be amended, renewed or cancelled at any time. This can be done verbally, in writing or through behaviour which clearly indicates this decision. It is not necessary for a person to have full legal capacity (i.e. in every domain) as a greater level of capacity is needed to write an advance directive than to cancel it. This has been discussed in medical circles as well as in literature on jurisprudence.

3.9.3 Access to information/diagnosis

3.9.3.1 The right to be informed

Section 5 of the Act on the Status and Rights of Patients, No. 785/92 of 17 August 1992 contains the following provisions regarding the patient's right to be informed:

"A patient shall be given information about his/her state of health, the significance of the treatment, various alternative forms of treatment and their effects and about other factors related to his/her treatment that are significant when decisions are made on the treatment given to him/her. However, this information shall not be given against the will of the patient or when it is obvious that giving the information would cause serious hazard to the life or health of the patient,

Healthcare professionals should try to give the information in such a way that the patient can understand it. If the healthcare professional does not know the language used by the patient or if the patient, because of a sensory handicap or speech defect, cannot be understood, interpretation should be provided if possible."

The above text can be interpreted as granting patients the right to be informed of the diagnosis.

Section 9.1 of the Act on the Status and Rights of Patients, "the right to be informed and the powers of the patient's representative", allows for information to be given to certain people in order to enable them to make decisions and consent on behalf of the person with incapacity. The text is as follows:

"In the circumstances referred to in paragraphs 2 and 3 of section 6, the patient's legal representative, close relative, or other person closely connected with the patient shall be entitled to receive any information regarding the patient's state of health that may be required to enable them to express an opinion and give their consent. (9.4.1999/489)"

3.9.3.2 Access to medical files

As a general rule, only the patient has access to his/her medical records.

Healthcare professionals and other people who are working in the medical domain cannot give information about a patient to outsiders without the written consent of the patient. (See Section 13 of the Act on the Status and Rights of Patients, No. 785/92.)

3.9.3.3 The right to designate another person to be informed on one's behalf

Under the government's proposal of the Act on the Status and Rights of Patients (185/1991) the legal representative is either a person appointed by a patient or a guardian (appointed by a court). If a patient has appointed someone to make healthcare decisions on his/her behalf (for example via an advance directive), such person has the right to be informed regarding the patient's state of health as stated in section 9.1 of the Act on the Status and Rights of Patients (see above). A patient can also appoint a "continuing power of attorney in healthcare issues" in advance of his/her incapacity (please see The Act on Continuing Powers of Attorney (648/2007)). Such donee is also a legal representative and also has the right to be informed under section 9.1 of the Act on the Status and Rights of Patients.

A legal representative (guardian), relatives and people who are close to the person with dementia can also be informed on his/her behalf although in their case, they would not actually have been designated by the person with dementia.

3.9.3.4 The doctor's right to withhold information

Section 5 of the Act on the Status and Rights of Patients, No. 785/92 of 17 August 1992 states that a doctor has the right to withhold information:

"when it is obvious that giving the information would cause serious hazard to the life or health of the patient."

See section "the right to be informed" above

3.9.3.5 The patient's right to refuse information

Section 5 of the Act on the Status and Rights of Patients, No. 785/92 of 17 August 1992 contains the following provisions regarding the patient's right to refuse information:

"...information shall not be given against the will of the patient."

See section "access to information" above

3.9.3.6 Confidentiality/disclosure of information to other people

Section 10 of the Constitution states that the private life, honour and home of every person shall be secured and that detailed provisions on the protection of personal data shall be prescribed by Act of Parliament. Patients must be treated in such a way that their human dignity is not violated and that their convictions and privacy are respected (section 3 of the Act on the Status and Rights of Patients, No. 785/92).

Apart from the exception contained in section 9.1 of the Act on the Status and Rights of Patients, information about patients is confidential. Section 13 of the Act on the Status and Rights of Patients (No. 785/92) covers the confidentiality of information in patients' medical files. As stated above in "the right to access medical files", healthcare professionals and other people who are working in the medical domain cannot give information about a patient to outsiders without the written consent of the patient. Section 13.3 of section 13 of this act includes further provisions:

1. information included in patient documents may be given if there are express provisions on giving it or on the right of access to it in the law;
2. information necessary for the arranging of examination and treatment of the patient may be given to another healthcare unit or healthcare professional, and a summary of the treatment provided may be given to the healthcare unit or the healthcare professional that referred the patient for treatment and to a physician possibly appointed to be responsible for the care of the patient in accordance with the patient's or his/her legal representative's oral consent or consent that is otherwise obvious from the context; and
3. information necessary for arranging and providing the examination and care of a patient may be given to another Finnish or foreign healthcare unit or healthcare professional, if the patient, owing to a mental health disturbance, mental handicap or for a comparable reason is not capable of assessing the significance of the consent and he/she has no legal representative, or if the patient cannot give the consent because of unconsciousness or for comparable reason;
4. information about the identity and state of health of a patient may be given to a family member of the patient or to another person close to the patient, if the patient is receiving treatment because of unconsciousness or for another comparable reason, unless there is reason to believe that the patient would forbid this; and
5. information on the health and medical care of a deceased person provided when the person was still living may be given, upon a justified written application, to anyone

who needs the information in order to find out his/her vital interests or rights, to the extent that the information is necessary for that purpose; the acquiring party may not use or forward the information for some other purpose.

Section 13 of the Act on the Status and Rights of Patients (30.6.2000/653) specifically addressed the issue of confidentiality of information contained in patients' records.

Paragraph 13.1 states that information contained in patients' records shall be confidential. Paragraph 13.2 states that healthcare professionals and other people working in or for healthcare units shall not disclose to outsiders information contained in a patient's medical records without the written consent of the patient. If the patient is not capable of giving such consent, it can be given by his/her legal representative. In this Act, the term "outsiders" refers to people other than those who are involved in the care of the patient or in carrying out tasks related to the person's care within or on behalf of a healthcare unit. The obligation to respect confidentiality remains in force even when the person is no longer employed or carrying out tasks on behalf of the healthcare unit.

3.9.4 End-of-life care and issues

3.9.4.1 Palliative care

Decisions about palliative care are made by a doctor but need to be discussed with the patient or patients' healthcare proxy/proxies.

3.9.4.2 Special leave for carers in paid employment

The Act on Support for Informal Care (937/2005) came into effect at the beginning of 2006. Support for informal care is a statutory social service. The municipality is responsible for organising the support within the limits of its resources.

The purpose of the Act is to promote informal care that is in the interests of the person cared for (the client) by securing sufficient access to social welfare and healthcare services and by safeguarding the continuity of care. Support for informal care encompasses necessary services for the client, and compensation, leave and support services for the informal carer.

In section 5.2 of the Act it is stated that if, during a heavy period of care (e.g. looking after a terminally ill person), a carer is unable to go to work, he/she receives a minimum allowance of EUR 600/month.

3.9.4.3 Euthanasia

Active euthanasia is not permitted.

A competent patient may, however, refuse life-saving or life-sustaining treatment or write in an advance directive the kind of treatment that he/she would like to refuse in the

future, should it be needed. Healthcare professionals who respect such wishes, which could be described as passive euthanasia, would not be prosecuted.

Healthcare proxies cannot forbid treatment which is necessary to ward off a threat to the life or health of the person they are representing.

3.9.4.4 Assisted suicide

Assisted suicide is not considered a criminal act under the Penal Code of Finland (39/1889 and subsequent amendments).

3.9.4.5 Homicide, murder and killing

The Penal Code of Finland (39/1889; amendments up to 650/2003 as well as 1372/2003, 650/2004 and 1006/2004 included) includes the following articles which are related to homicide and murder:

Chapter 21 - Homicide and bodily injury (578/1995)

Section 1 - Manslaughter (578/1995)

- (1) A person who kills another shall be sentenced for manslaughter to imprisonment for a fixed period of at least eight years.
- (2) An attempt is punishable.

Section 2 - Murder (578/1995)

(1) If the manslaughter is

- (1) premeditated;
- (2) committed in a particularly brutal or cruel manner;
- (3) committed by causing serious danger to the public; or
- (4) committed by killing a public official on duty upholding the peace or public security, or because of an official action;

and the offence is aggravated also when assessed as a whole, the offender shall be sentenced for murder to life imprisonment.

- (2) An attempt is punishable.

Section 3 - Killing (578/1995)

- (1) If the manslaughter, in view of the exceptional circumstances of the offence and the motives of the offender or other related circumstances, when assessed as a whole, is to be deemed to have been committed under mitigating circumstances, the offender shall be sentenced for killing to imprisonment for at least four and at most ten years.

- (2) An attempt is punishable.

Section 8 - Negligent homicide (578/1995)

A person who through negligence causes the death of another shall be sentenced for negligent homicide to a fine or to imprisonment for up to two years.

Section 9 - Grossly negligent homicide (578/1995)

If in the negligent homicide the death of another is caused by gross negligence, and the offence is aggravated (also when assessed as a whole), the offender shall be sentenced for grossly negligent homicide to imprisonment for at least four months and at most six years.

3.9.5 Bibliography

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3.10 France

3.10.1 Background to healthcare system and patients' rights

The healthcare system has been the subject of substantial legislative reforms in France for the last 15 years, resulting in the progressive recognition of the rights of vulnerable persons. This new legal framework consists of several pieces of legislation that, depending on the case, apply to strictly medical situations (e.g. a hospital stay related to a medical procedure etc.) and/or to care and support by social or socio-medical organizations (e.g. retirement facilities, services at home etc.).

We should note that the affirmation of fundamental health rights is most often the result of transposing into French law principles and values set out at the European or international level (e.g. the Universal Declaration of Human Rights of 10 December 1948, the European Convention on Human Rights of 4 November 1950, the Charter of Fundamental Rights of the European Union of 7 December 2000). Other sources with more limited legal scope complete the French standard-setting framework, such as the medical code of ethics and other ethical charters and professional guidelines.

The recognition of a general and absolute right to health protection is thus stated in article L. 1110-1 of the Code de la santé publique (French public health code):

"The fundamental right to health protection must be implemented by all available means for the benefit of all persons".

Since 2002, two pieces of legislation (Law No. 2002-2 of 2 January 2002 and Law No. 2002-303 of 4 March 2002) have reinforced several ethical principles in the French healthcare system such as respect of dignity, privacy and intimacy, the right to be informed, freedom of choice, informed consent, non-discrimination, the right to be protected and freedom of movement etc.

3.10.2 Consent

3.10.2.1 Consent to treatment

The recent reforms related to the right to health have sought mainly to restore the place of the patient's wishes at the heart of the care system. Seeking the consent of the person who is ill is thus the prerequisite for any treatment.

Article L. 1111-4 of the French Public Health Code stipulates in effect:

"that no medical act and no treatment can be practiced without the free and informed consent of the person and this consent may be withdrawn at any moment."

This is because the human body is inviolable, and cannot be infringed upon without consent. The principle is already stated in the Code Civil (French civil code):

Article 16-1 states:

"Everyone has the right to respect for his/her body. The human body is inviolable ..."

Article 16-3 states:

"An attack may be made on the integrity of the human body only in the event of therapeutic necessity for the person."

"The prior consent of the interested party must be received except in those cases where his or her conditions necessitate a therapeutic action to which he or she is not in a fit state to consent."

In addition, general provisions surrounding the issue of consent can be found in article 36 of the Code of Medical Ethics⁷:

"The doctor must in all cases attempt to obtain the consent of the person examined or provided with care."

"When the patient, while in such a condition that s/he is able to express his/her will, refuses the proposed investigations or treatment, the doctor must respect that refusal after informing the patient of its consequences."

"If the patient is not in a fit condition to express his/her will, the doctor may only take action after warning and informing those close to the patient, except in emergency cases or in cases where it is impossible so to warn and inform."

"The obligations of the doctor with regard to the patient when s/he is a minor or a protected person of full age are defined in article 42."

Patients have the right to accept or refuse treatment. In order to be in a position to give informed consent, they must also be fully informed about what is involved and the consequences of the treatment. The obligation to inform the patient is covered by article L. 1111-2 of the French Public Health Code:

"everyone has the right to be informed about the state of his/her health."

In the event of litigation, article L. 1111-2 paragraph 7 of the Public Health Code stipulates that the health professional or institution is responsible for furnishing proof that the information has been given to the person concerned [...]. The proof can be furnished in any form.

Written consent is not obligatory but it is often requested for important decisions. In some hospitals, written consent (permission to operate) is systematically requested. It does not have legal value, except in cases where it is legally required (e.g. in the case of biomedical research – Law of 20 December 1988). However, due to recent court cases⁸ the doctor must be able to prove that he/she has provided the patient with the relevant

7 Decree No. 95-1000 of 6 September 1995 on the Code of Medical Ethics

8 e.g. Ruling of the Cour de Cassation of 25 February 1997

information in order to give informed consent. Consequently, doctors are increasingly requesting written consent. Nevertheless, it is not clear what the situation is concerning people who are unable to consent, i.e. whether the courts could demand proof that the patient's guardians had been informed.

3.10.2.2 Consent in the case of incapable adults

The doctor who performs a medical act without the patient's consent is likely to engage his/her civil, legal and disciplinary responsibility. In the case of adults unable to make informed decisions, it must be ascertained whether or not they are under some form of guardianship.

If the person is unable to express his or her wishes but does not have a legal guardian, no action or investigation can be carried out without consulting a healthcare proxy, family member or friend (unless this is impossible, or in an emergency) (article L 1111-4 in the Public Health Code, article 16-3 in the civil code). The doctor listens to this opinion, but is not bound to follow it.

If the person has a guardian, it is the legal representative who consents to the treatment, although the consent of the protected adult must be sought systematically, to the degree that the person is able to express his/her wishes and participate in the decision.

3.10.2.3 Consent in case of emergency

In addition, general provisions surrounding the issue of consent can be found in one of the paragraphs of article 36 of the Code of Medical Ethics⁹:

".../...If the patient is not in a fit condition to express his will, the doctor may only take action after warning and informing those close to the patient, except in emergency cases or in those where it is impossible so to warn and inform./..."

3.10.2.4 The right to refuse treatment

If a patient refuses treatment, the doctor must respect this decision. Nevertheless, he/she must make sure that the patient is aware of the consequences of this decision and try to convince the patient that the proposed treatment is in his/her best interests. If the patient remains firm in his/her refusal and the doctor is of the opinion that failure to have the treatment would be dangerous for the patient, he/she must suggest that they obtain a second opinion and insist on the necessity of the treatment. If the patient will not change his/her opinion, the doctor must not abandon the patient and must ensure that he/she continues to receive care should this be the patient's request.

3.10.2.5 The right to withdraw consent

Requiring free and informed consent in any treatment procedure implies that consent can be withdrawn at any time (article L. 1111-4, par. 3 of the Public Health Code).

3.10.2.6 Consent to the donation of organs and/or human tissue

The laws on bioethics of 1994 and 2004 provide a new framework for organ donation which aims to reconcile the need for organs with the necessity to avoid the trafficking of organs.

Organs may only be removed from a deceased person for therapeutic or scientific purposes and provided that the person did refuse such removal during his/her lifetime. If the doctor does not have direct knowledge of the wishes of the deceased person, he/she must endeavour to find out what they were from people who were close to the latter (L1232-1 of the Public Health Code).

If the deceased person was an adult who was under guardianship ("tutelle"), the organs may only be removed with the written consent of the guardian ("tuteur").

3.10.2.7 Consent to non-conventional treatment

No specific legal provisions in French law.

3.10.2.8 Consent to research

Article L. 1122-1-1 of the Public Health Code stipulates

"that no biomedical research can be carried out on a person without his free and informed consent, obtained after the information has been delivered to him. The consent is given in writing, or, when this is not possible, certified by a third party. The latter must be totally independent of the investigator and of the promoter."

Regarding the consent of vulnerable persons, it is appropriate to ascertain whether or not a legal means of protection has been established.

When the person is not covered by a system of legal protection, but lacks the capacity to express consent,

"authorization is given by the healthcare proxy ("personne de confiance"), or in his absence by the family, or in their absence by a person who has close and stable ties to the person" (article L1122-2 II of the Public Health Code).

When there is substantial risk, the guardianship judge gives the authorization. It is important to note that the French system now allows biomedical research even when the vulnerable persons are not covered by a system of legal protection, which was impossible prior to the 9 August 2004 law.

When research is carried out on an adult who has a legal guardian ("tutelle"), the consent is given by the guardian.

If the "Comité de protection des personnes" (research ethical committee mandated to evaluate and approve in advance all biomedical research protocols) considers that there is significant risk of violating privacy or the integrity of the human body, authorization may be given by the guardianship judge (or the *Conseil de famille*, family council, if there is one).

When research is carried out on an adult who has a legal guardian under the “*curatelle*” system, the person gives his/her consent with the assistance of his/her guardian. In the event of a high level of risk, the guardianship judge is called on to determine the adult’s ability to give consent. If the adult is unable, the judge decides whether or not to authorize the research.

An adult under “*sauvegarde de justice*” (temporary court-ordered legal guardianship) may not participate in biomedical research.

We must note, however, that the opinion of the vulnerable person participating in the research must always be heard. The person must indeed “*be consulted to the degree that their state permits*” and seeking their “personal commitment” is mandatory (article L1122-2 of the public health code).

The researcher informs the person whose consent is sought of his/her right to refuse to participate in the research or to withdraw his/her consent at any time, without incurring any liability or penalty.

The information communicated is resumed in a written document delivered to the person whose consent is sought. When the research is complete, the person who has been a subject has the right to be informed of the global research results, according to terms set out in the information document.

3.10.2.9 Approval for biomedical research

According to article L. 1121-4 of the Public Health Code, it is mandatory that any biomedical research protocol be examined by a *Comité de Protection des Personnes* (CPP) (research ethical committee) and be approved before it is initiated. The committee gives its opinion on the project’s validity.

In contrast, no specifications are given for certain research projects termed “non-interventional”, notably in the human and social sciences, which do not fall into the CPP’s present field of competence. Some additional administrative authorizations may be required, often in the form of preliminary declarations (notably a declaration to the *Commission nationale de l’informatique et des libertés* – Law No. 78-17 of 6 January 1978 pertaining to data privacy – for any electronic processing of personal data). Yet these administrative procedures in no way constitute a global and multidisciplinary evaluation of research protocols, and only “common” legislations regulate their practice (information, obtaining consent and protection of personal data privacy).

3.10.3 Advance directives

3.10.3.1 The legal status of advance directives

Since 2005, article L. 1111-11 of the Public Health Code allows any adult to write advance directives in preparation for the day he/she will no longer be able to express his/her wishes.

3.10.3.2 Conditions surrounding the writing, validity and registration of an advance directive

They take the form of a written document, dated and signed, which can be revoked at any time. The directives can be kept in the medical file for easy access, or remain in the patient's possession or that of his/her healthcare proxy ("personne de confiance").

3.10.3.3 What an advance directive can cover

These directives allow anyone to express their wishes about end-of-life care and limiting or stopping treatment, in case the person becomes unable to communicate his/her decisions.

3.10.3.4 Obligation to comply with instructions contained in an advance directive

The doctor is not bound by advance directives when he/she decides whether or not to limit or stop treatment. Nonetheless, the doctor is obligated before s/he makes his/her decision to initiate a "collegial procedure" in which the advance directives must be taken into account (article L. 1111-13 of the Public Health Code).

On the condition that they were drafted less than three years before the person became incompetent, the doctor takes them into account in all decisions concerning investigation, medical procedure or treatment. But although the law gave them a lifespan of only three years, it should be noted that the spirit of earlier wishes endures, particularly when no new advance directives are written after three years.

3.10.4 Access to information/diagnosis

3.10.4.1 The right to be informed

The obligation to inform the patient can be explained by the need to obtain his/her free and informed consent beforehand. Several texts confirm this obligation.

The following paragraphs are taken from article 35 of the Code of Medical Ethics:

"The doctor must provide the person whom he examines, to whom he provides care or whom he advises, with honest, clear and suitable information concerning his condition and the investigations and care which he proposes. Throughout the duration of the disease, he must take into account the personality of the patient in his explanations and make sure that they understand them. (.../....)"

However, in the interests of the patient and for legitimate reasons which the practitioner is to judge carefully, a patient may be kept in ignorance of a serious diagnosis or a prognosis, except in cases where the case or the illness from which s/he is suffering exposes third parties to a risk of contamination.

A fatal prognosis should only be revealed circumspectly, but persons close to the patient must be warned, unless the patient has previously forbidden such revelation or has designated those third parties to whom it must be revealed."

Article L. 1111-2 of the public health code thus states that "*everyone is entitled to be informed about his/her state of health*".

This obligation to inform falls on the doctor for everything concerning medical procedures, but the obligation also applies to paramedical staff. This is specified in article L. 1111-2 of the Public Health Code: "*this (obligation to inform) is incumbent upon every health professional in the context of his proficiencies and in compliance with the professional rules applicable to him. He can be exempted only in cases of emergency or impossibility of informing.*"

The first recipient of this information must be the patient, because the rule of medical confidentiality calls for this solution. Yet according to article L. 1110-4 par. 6 of the Public Health Code, if the prognosis or diagnosis is serious, the rule of medical confidentiality allows for the family or healthcare proxy to receive the information, unless the patient objects.

When the person has a legal guardian ("tutelle"), the guardian receives the information. The doctor must nonetheless inform the patient, in a manner appropriate to his/her ability to understand: "*the rights of adults under guardianship mentioned in the present article are exercised by the guardian. The latter receives the information called for in the present article, subject to the clauses of article L. 1111-5 of the Public Health Code. The people concerned have the right to receive information themselves and to participate in making decisions that affect them, in a way that is appropriate to their capacities for understanding.*" (L. 1111-2 of the Public Health Code)

The information is imparted during an individual interview, in a clear and comprehensible way. This does not preclude the delivery of written documents to the patient.

In the event of disputes, the burden of proof in terms of information is now reversed. Article L. 1111-2, al.2 of the public health code states in effect that it is the doctor who must prove that he/she gave information and received consent. This proof can be furnished in any form.

3.10.4.2 Access to medical files

According to article L. 1111-7 of the Public Health Code, communication of the medical file is an obligation for the healthcare facility and a right for the patient. This communication can take place directly or with a designated doctor as the intermediary.

"Everyone has access to all information concerning his/her health." (Article 1111-7)

In practice, the French Public Health Code sets out very precise rules on modalities for disclosing the contents of the medical file (article R.1111-1 of the Public Health Code and following). For example, when the patient is in a healthcare facility, a written request must be sent to the hospital director or department head. The communication can take place on the premises or by sending copies of requested documents, in compliance with ethical rules covered by medical confidentiality.

3.10.4.3 The right to designate another person to be informed on one's behalf

3.10.4.3.1 "Personne de confiance" (healthcare proxy)

The possibility of designating a healthcare proxy, called in France a "*personne de confiance*", has existed since 2002. As article L. 1111-6 of the Public Health Code states,

"any adult may designate a healthcare proxy who can be a relative, a friend or their doctor, and who will be consulted should the person concerned be unable to express his wishes and to receive information necessary for this purpose. The designation is done in writing. It can be revoked at any time. If it is the wish of the person who is ill, the healthcare proxy accompanies him at every step and is present at medical appointments to help him reach decisions."

This designation can therefore take place at any moment, when the person is legally competent, well before hospitalization or admission to a social or socio-medical care facility.

To encourage people to appoint healthcare proxies, the law demands that in the event of hospitalization, the healthcare facility must suggest that the patient name a healthcare proxy for the duration of the hospital stay. The patient is free to refuse or agree to choose a healthcare proxy. This obligation to make the suggestion systematically at the time of admission, however, does not apply to social and socio-medical facilities.

When the patient is under a system of legal protection, the possibility of naming a healthcare proxy varies according to the measures of protection. If the person who is ill is under special partial guardianship – "*sauvegarde de justice*" or "*curatelle*" – the vulnerable adult may still appoint a proxy. If the person is under "*tutelle*" (general guardianship), it makes a difference whether the healthcare proxy was named before or after the guardianship decision. If the designation followed the guardianship, it is invalid. In the event that the designation preceded the guardianship, the healthcare proxy's mission must be confirmed or invalidated by the guardianship judge.

Concerning the healthcare proxy's role, let us remember that from a legal point of view, the healthcare proxy does not have the power to decide in the place of the patient who cannot express his/her wishes. In effect, from a simple supportive role during medical interviews and the consultation of the medical file, the healthcare proxy ends up with a simple consulting role in any medical procedure or treatment once the person does not have the ability to express his wishes. At the end of life, the proxy's opinion must be sought when the doctor initiates the "collegial procedure", but the doctor does not have to follow it. The only exception is biomedical research, which the healthcare proxy has the power to authorize (article L. 1122-1-2 and 1122-2, II of the Public Health Code).

The "healthcare proxy" measure does not therefore establish genuine "medical representation" or a "mandate" in the sense of the French civil code: at most, the healthcare proxy is the "voice" of the vulnerable.

3.10.4.3.2 "Mandat de protection future" (mandate of future protection or power of attorney)

By creating a "mandat de protection future", the recent law (5 March 2007) reforming the legal protection of adults introduced a potential new interlocutor in health law. This mandate allows any competent person (or under "curatelle" guardianship with the help of his guardian) to designate, in view of a time when the person will no longer be able to manage his own life unaided, one or several other people to act as his representatives in all personal matters.

Derived either from a notarized mandate or a private agreement, the representative's powers can be more or less extensive. This representation could cover financial as well as medical issues, as the mandate could apply to property and/or personal rights. Regarding health, the representative could also take on all the tasks performed by the guardian or the healthcare proxy, within the framework of the duties assigned to the guardian or the healthcare proxy by the Public Health Code and the "*Code de l'action sociale et des familles*", the French social action and family code. The representative could for example authorize research, consent to a medical procedure or receive medical information.

3.10.4.4 The doctor's right to withhold information

According to article 35 of the Code of Medical Ethics:

".../... However, in the interests of the patient and for legitimate reasons which the practitioner is to judge carefully, a patient may be kept in ignorance of a serious diagnosis or a prognosis, except in cases where the case or the illness from which he is suffering exposes third parties to a risk of contamination."

A fatal prognosis should only be revealed circumspectly, but persons close to the patient must be warned, unless the patient has previously forbidden such revelation or has designated those third parties to whom it must be revealed."

3.10.4.5 The patient's right to refuse information

Article L. 1111-2 al 4 of the public health code states that "*the wish of a person to remain ignorant of a diagnosis or a prognosis must be respected, except when others are at risk from transmission.*"

3.10.4.6 Confidentiality/disclosure of information to other people

According to article L. 1110-4 of the public health code, medical confidentiality applies to all healthcare professionals, as well as to all professionals (non-medical staff) working in the healthcare system:

"Any person taken into the care of a professional, an institution, a health network or any other body participating in prevention and care has the right to respect for his privacy and for the confidentiality of information concerning him."

The obligation to maintain secrecy is also stipulated in article 4 of the Code of Medical Ethics. It states:

"Professional secrecy, instituted in the interests of the patient, is required from all doctors under the conditions imposed by law.

Secrecy covers everything which comes to the knowledge of the doctor in the exercise of his/her profession; that is to say not only information which is given to him or her but also what he or she has seen, heard or understood."

3.10.5 End-of-life care and issues

3.10.5.1 Palliative and end-of-life care

Since 1999 and in addition to a French Palliative Care Plan implemented in 2002, the law stresses that doctors safeguard the patient's dignity by ensuring palliative care. It thus reaffirms the right to palliative care, which consists of active and continuous treatment from a multidisciplinary team, in cooperation with volunteers who provide support, within a care facility or at home. The purpose of this care is to relieve pain, to calm psychological suffering, to safeguard the person's dignity and to support his/her family and friends. The goal is to ensure the highest possible quality of life until death. Palliative care is organized through all the different care systems within healthcare facilities, at home and in different socio-medical institutions and services.

However, according to article 37 of the Code of Medical Ethics, the doctor must make every effort to ease the suffering of his/her patient, provide moral support and avoid unreasonable persistence in examinations or therapy. Article 38 of this code states that the doctor does not have the right to deliberately bring about the death of a person. Moreover, it is the doctor's duty to accompany the dying person in his/her last moments, to ensure the appropriate kind of care and attention, safeguard the dignity of the patient and comfort his/her entourage.

Concerning end-of-life situations, French law does not allow euthanasia. Since 2005, the 22 April 2005 law defines the framework surrounding end-of-life situations and condemns "unreasonable obstinacy". Article L. 1110-5 of the public health code indeed clearly states that the doctor "*must strive to relieve the suffering of the patient by means appropriate to his state and to give him moral support. He must abstain from all unreasonable obstinacy in investigation and treatment and may withhold or end treatment that appears pointless and disproportionate, or have no other purpose except the artificial maintenance of life.*"

When the patient is unable to express his/her wishes, the doctor may not decide to withhold or end treatment without first having initiated a "collegial procedure", with the imperative aim of collecting the opinions of others (the care giving team, another physician, the healthcare proxy, relatives and friends, as well as consideration of the advance directives).

3.10.5.2 Assisted suicide and non assistance to a person in danger

There is no actual law forbidding assisted suicide in the French penal system. However, helping someone to commit suicide can be assimilated into the law concerning the non-assistance of a person in danger. According to article 223-6 of the Penal Code, a person who does not offer assistance or seek help for a person who is in danger of his/her life, receives the same punishment as a person who could but does not prevent a crime against another person.

In 1988 in response to a guide to suicide, the government added two new articles to the Code to cover provoking suicide. Part one of article 223-13 of the Penal Code is relevant in that it states that:

"The provocation of another person to commit suicide is punished by three years' imprisonment and a fine of € 45,000 where the provocation was followed by a suicide or attempted suicide."

3.10.5.3 Murder

Euthanasia is assimilated into homicide in the French penal code. The relevant extracts of the Penal Code are as follows:

Article 221-1

"The wilful causing of the death of another person is murder. It is punished with thirty years' criminal imprisonment."

Article 221-3

"Murder committed with premeditation is assassination. Assassination is punished by a criminal imprisonment for life."

Article 221-5

"Making an attempt on the life of another person by the use or administration of substances liable to cause death constitutes poisoning and is punished by 30 years' imprisonment."

Article 122-2

"A person who acted under the influence of a force or a constraint which he or she could not resist is not criminally responsible."

3.11 Germany

3.11.1 Consent

3.11.1.1 Consent to medical treatment

In the Professional Rules for German Doctors¹⁰, the following two paragraphs are relevant to the issue of consent:

§ 7.1

In all medical treatment, human dignity must be ensured and the personality, will and rights of the patients, in particular the right of self-determination must be respected.

§ 8

In order to provide treatment a doctor requires the consent of the patient. In principle consent must be preceded by the necessary explanation in personal discussion.

The issue of consent is dealt with by numerous high level Court decisions which have consequently set precedents. A basic principle is that any treatment carried out on a person against his/her will constitutes bodily injury. For this reason, consent is necessary in all cases. If the person undergoing treatment is unable to consent, in certain cases the decision can be taken by a legal representative.

According to § 1904 of the Civil Code, the guardian can consent to health examinations, medical treatment or surgery, but must obtain authorisation from the Guardianship Court if there is a reasonable risk that the ward could die as a result of the measure or might suffer from serious and more prolonged damage to health. Nevertheless, if not carrying out the measure immediately would endanger the health of the patient, it can be carried out without prior authorisation.

Whether a person is capable of consent is not based on legal criteria but rather on whether a person can understand the consequences of an intervention or treatment for his/her body, profession and private life (Laufs, 1993¹¹). It is not always possible to determine whether a person has this capacity.

3.11.1.2 Appointment of a healthcare proxy

A person who has capacity can appoint a healthcare proxy in an advance directive.

3.11.1.3 Consent in case of emergency

In an emergency situation, a doctor must decide on the basis of the presumed will of the patient. In order to determine what this might be, he/she should ask relatives and then respect this will. Even if the presumed will of the patient seems unreasonable (e.g. declining a blood transfusion on religious grounds), it must still be respected (Winterstein, 1997 – see footnote 11). If it is not an emergency but the patient is unable to consent, the doctor should contact the Guardianship Court in order to appoint a guardian, rather than rely on relatives to make the decision.

¹⁰ The Professional Rules for German Doctors quoted in this report are part of the model version which was decided upon at the 100th German Medical Parliament in Eisenach in 1997. They take on legal validity when adopted at the council meetings of the State Chamber of the Medical Council and approved by the supervisory authorities. They are legally binding for doctors who are members of the chamber in their respective "Land". Membership of such a chamber is obligatory and there are only marginal differences between the model rules and the actual rules adopted by the chamber in each Land.

¹¹ In: Wächtler, C. (1997), Demenzen: Frühzeitig erkennen, aktiv behandeln, Betroffenen und Angehörige effektiv unterstützen, Thieme Verlag.

3.11.1.4 Consent to research and clinical trials

The issue of protecting research subjects involved in pharmaceutical trials is addressed in a special paragraph in the Medicines Act. The following restrictions apply according to this law (Leenen et al., 1993):

- anybody participating in such research must have given informed consent;
- anybody who has been involuntarily committed cannot participate;
- only therapeutic research is possible in the case of incompetent people.

The restriction regarding therapeutic research is important for practically all areas of research in Germany. In fact, the main reason why Germany did not sign the Convention on Human Rights and Biomedicine (Council of Europe, 1997) was that it contains a clause which allows in certain circumstances for non-therapeutic research to be carried out on people lacking the capacity to consent, i.e. research which does not have the potential to produce results of direct benefit to the health of the person concerned.

3.11.2 Advance directives/living wills

3.11.2.1 The legal status of advance directives in Germany

Since 1.9.2009 advance directives have been legally recognised. The new law is integrated into Book 4 of the Civil Code, §§ 1901 a + b (Family Law, Section 3, Heading 2, Legal Guardianship). The new law recognises that advance directives reflect a citizen's right to self-determination and are linked to the issue of consent to treatment. Therefore, it is possible for people to refuse or limit specific treatments in advance of their incapacity by means of advance directives.

An advance directive may in certain circumstances be considered as binding e.g. if there is no indication of a change of will related to the specific situation and if the instruction is based on sufficient medical information for the medical treatment proposed. In such cases, a decision that is clearly in favour of withdrawing treatment and is clearly the manifest desire of the patient must be complied with (Council of Europe, 2003).

3.11.2.2 Conditions surrounding the writing, validity and registering of an advance directive

An advance directive can only be written by an adult who has capacity and is not subject to external pressure. For example, writing an advance directive cannot be made a condition for concluding a contract. The advance directive must be in written form. It is assumed that a person has capacity but confirmation of this by a notary may be helpful. The advance directive should refer to specific treatment or situations and cannot include a request for something that is illegal, e.g. assisted suicide. Advice from a doctor is advisable but not necessary. There is no set procedure for registering advance directives and they are not limited to a set period of time.

3.11.2.3 What an advance directive can cover

An advance directive can cover medical investigations, treatment and/or medical interventions.

3.11.2.4 Obligation to comply with instructions contained in an advance directive

If a person has a guardian, the guardian has to check that the previously expressed wishes relate to the current situation and if so, to ensure that those wishes are respected. The doctor and the guardian have to discuss the wishes contained in the advance directive in order to come to a decision about treatment.

People who are close to the patient and other trusted persons should be heard provided that this would not result in considerable delay.

It is often difficult for doctors to determine whether instructions/wishes expressed in an advance directive correspond to the current situation. For some, it is also unclear whether failure to initiate or end life-supporting treatment/measures is permitted or, on the contrary, fulfils the criteria for the criminal offence of "murder at the request of the victim" (Mathy and Godschalk, in Alzheimer Europe, 2006). The new law does not seem to offer any clarity on this issue.

3.11.2.5 Amending, renewing and cancelling advance directives

An advance directive can be withdrawn at any time. It is not stated that a person has to have full legal capacity to do this.

3.11.2.6 Previously expressed wishes in the absence of valid advance directive

Paragraph 1901a does, however, outline the obligation of guardians to take into account previously wishes in cases where the person lacking capacity did not make an advance directive or made one but it does not apply to the current situation. In doing so, guardians must base their appraisal of the person's wishes on concrete evidence such as wishes which were previously expressed either in writing or orally, ethical or religious convictions and known personal values. This must be done irrespective of the stage or type of illness that the person has.

3.11.3 Access to information/diagnosis

3.11.3.1 The right to be informed

The obligation to provide information to patients is based on the need to justify the reason for the treatment and to inform the patient of any possible risks, consequences or side effects. According to the highest judicial authorities, information must be "by and large" provided. This means that the kind of information to be supplied depends on each individual and his/her particular medical case (Leenen et al., 1993).

3.11.3.2 Access to medical files

Under § 242 of the Civil Code, patients have a right to access their medical files and do not need to justify the request. If, however, information has been provided by third parties, this access may be restricted.

As mentioned earlier, the doctor is obliged according to § 8 of the Professional Rules for German Doctors to provide the patient with information in order to enable the latter to give informed consent. In § 10 it is stated that the doctor must grant access to the patient's medical files. However, those parts that contain the doctor's subjective impressions or perceptions are excluded from this. A fee may be charged for the provision of copies of these records. It is not stated whether such access can be granted to third parties.

3.11.3.3 The right to designate another person to be informed on one's behalf

If a healthcare proxy has been designated in an advance directive, this person would also be entitled to receive information on behalf of the person.

3.11.3.4 Confidentiality/disclosure of information to other people

§ 9 of the Professional Rules for German Doctors obliges doctors to maintain confidentiality in respect of any information that is entrusted to him/her in his/her capacity as a doctor. This obligation exists even after the death of the patient.

The disclosure of personal information to third parties is prohibited by § 823 of the Civil Code which governs the protection of personal rights. The issue of privacy is also addressed in the Penal Code. Paragraph 203 states that it is a punishable offence for anyone to reveal without authorisation a fact that another person told in confidence due to the former's professional capacity. This applies to doctors, dentists, veterinary surgeons, pharmacists, members of a state-controlled and recognised medical profession and professional state-recognised psychologists. It also applies to assistants of the latter acting on a professional basis and those working for them in preparation for the profession.

3.11.4 End-of-life care and issues

3.11.4.1 Euthanasia/palliative care

The following instructions on "aid to the dying" can be found in § 16 of the Professional Rules for German Doctors:

"A doctor – giving priority to the wishes of the patient – may refrain from life-prolonging measures and restrict him/herself to the alleviation of pain only if the postponement of the inevitable death of the dying person would merely mean unreasonable prolongation of suffering. A doctor must not actively shorten the life of the dying person. He/she must not place his own interest or the interest of third parties above the wellbeing of the patient."

The above paragraph which addresses the issue of both passive and active euthanasia does not refer to incapacitated people or to previously expressed wishes. It is therefore unclear what the doctor's obligation would be in the case of an incapacitated person.

3.11.4.2 Assisted suicide

The issue of assisted suicide and active euthanasia is also addressed in the Penal Code. A person who deliberately incites another person to commit an illegal act is guilty of "complicity before the act" according to paragraph 26 of the Penal Code. If the person voluntarily helps another to commit an illegal act, he/she is considered as an accomplice according to paragraph 27. However, neither of these laws is applicable in the case of assisted suicide due to the fact that suicide is not considered a punishable offence. Nevertheless, there are certain conditions. The person who commits suicide must have acted according to the principle of "Tatherrschaft" which means that he/she must have been able to control his/her actions, have been capable of acting in a responsible manner and have acted freely without coercion.

3.11.4.3 Non-assistance to a person in danger

On the other hand, paragraph 323c of the Penal Code which deals with failure to provide assistance, states that it is an offence not to provide assistance to a person in case of accident, common danger or urgency. This is particularly relevant for doctors whose duty it would be to provide assistance and try to reanimate a person who had committed suicide as soon as the latter became unconscious.

3.11.4.4 Murder at the request of the victim

Euthanasia is illegal in that it could be classed as either murder, manslaughter or murder at the request of the victim – all of which are liable to entail a prison sentence. In the case of euthanasia, murder at the request of the victim (*Tötung auf Verlangen*) is the charge frequently brought against the perpetrator of the act. This act (paragraph 216 of the Penal Code) states:

"Whoever causes the death of another person after having been expressly and sincerely asked to do so by this other person, is liable to a prison sentence of 6 months to five years.

The attempt is also punishable."

3.11.5 Bibliography

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3.12 Greece

3.12.1 Consent

3.12.1.1 Consent to medical treatment

Article 12 of the Code of Medical Ethics of 2005¹² states: "the physician shall not proceed with the execution of any medical act, unless consent has been secured" (Goffin et al., 2007). However, for consent to be considered as valid, certain conditions must be fulfilled. The patient must have been fully informed (according to article 11) and have the capacity to consent. The consent must not have been made under duress or as a result of fraud or a mistake. However, for trivial interventions which do not involve any risk, consent can be presumed (Goffin et al., 2007).

3.12.1.2 Consent to treatment (for people with incapacity)

Consent in the case of people with incapacity is covered by Article 11 of the Code of Medical Ethics which states, "if a patient is not competent, consent for a medical treatment is given by the legal representative if appointed; if this is not the case, consent is given by relatives of the patient. In any case, the physician must try to obtain the voluntary participation and cooperation of the patients, especially of those patients who understand the status of health and their nature, consequences, results and risks of a treatment" (Goffin, 2007, p.18).

3.12.1.3 Consent in case of emergency

In emergency situations where the doctor cannot obtain informed consent s/he is obliged to provide the necessary treatment without consent. This is covered by articles 441 and 473 of the Penal Code.

3.12.1.4 The right to refuse treatment

Article 47 (3) of the Hospital Act of 1992 grants every patient the right to refuse consent to any diagnostic or therapeutic procedure but this is presumably limited to patients who have the capacity to consent and presumably extends to the legal representatives of those who do not.

Article 9 of the Biomedicine Convention is applicable with regard to previously expressed wishes because article 12 of the former Code of Medical Deontology, which forbade doctors from taking into account previously expressed wishes, was not included in the Code of Medical Ethics of 2005 which replaced it, and as Greece had ratified the Convention without any reservation regarding article 36.

3.12.1.5 Consent to the donation of organs and/or human tissue

The guardian may consent to the donation of the brain of a relative suffering from Alzheimer's disease for post mortem examination at university laboratories (Lecca Marcati, 1999).

3.12.1.6 Consent to research

Article 47 of the Hospital Law of 1992 (2071) states that the patient must feel free to decide whether he/she wants to take part in research or training. Consequently, consent must be obtained and can be withdrawn at any time. This applies to the patient's proxy if the patient is totally or partially incapacitated (Lecca Marcati, 1999).

3.12.2 Advance directives and healthcare proxies

Doctors were previously not allowed to take advance directives into consideration due to article 12 of the Code of Medical Deontology. However, Greece has ratified the Biomedicine Convention and did not make any reservation about article 9 which states:

The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account.

Consequently, according to Goffin et al. (2007), article 9 of the Convention overrules article 12 of the Code of Medical Deontology due to the wider scope of the former. Furthermore, the Code of Medical Deontology was revised in 2005 and ratified by statue thereby becoming Law No. 3418/2005. It does not contain an article which deals with previously expressed wishes. This further confirms the applicability of article 9 of the Biomedicine Convention (Goffin et al., 2007).

Nevertheless, it should be noted that article 9 of the Biomedicine Convention does not render advance directives legally binding but rather states that previously expressed wishes must be taken into account.

3.12.3 Access to information/diagnosis

3.12.3.1 The right to be informed

According to article 47 of the Hospital Law, patients have the right to request and receive accurate and comprehensive information on their state of health. They must be provided with sufficient information to enable them to form a clear understanding of the medical, social and financial issues surrounding their condition, to enable them to make their own decisions or at least to participate in the decision-making process. Thorough information must be given about risks which might arise as a result of unusual or experimental therapeutic procedures. Such information can be provided to a patient's legal representative.

Article 11 of the Code of Medical Ethics of 2005 makes it the doctor's duty to fully and comprehensively inform patients about their health status, probable results and risks of treatment, side-effects, alternatives etc. The doctor is obliged to inform people who are unable to consent as much as possible.

3.12.3.2 Access to medical files

Patients are entitled to access their medical file and to receive a copy of the file (article 14 (8) of the Code of Medical Ethics) but not to written documents covered by medical confidentiality concerning other people (article 16 of the Act 1599/1986 on Citizen/State relations) (Goffin et al., 2007).

3.12.3.3 The right to designate another person to be informed on one's behalf

Legal representatives who are authorised to consent on behalf of a person with incapacity must also be informed by the doctor (article 11 (4) of the Code of Medical Ethics, 2005). Patients are entitled to designate a person to receive information on their behalf (Article 11 (2) of the Code of Medical Ethics). The designated person should receive the same information as the patient would have received.

3.12.3.4 The doctor's right to withhold information

It is the doctor's duty to tell the patient the truth, although he/she can partly reveal or hide the truth in cases of unfavourable prognoses, the revelation of which could cause serious or irreversible damage to the patient's health. However, the onus would be on the doctor to prove this.

3.12.3.5 The patient's right to refuse information

Patients are entitled to refuse information and may ask the doctor to inform a person that they have designated (Article 11 (2) of the Code of Medical Ethics).

3.12.3.6 Confidentiality/disclosure of information to other people

According to article 2 of the Greek Constitution, respect for and protection of human dignity constitute the primary obligation of the State. This is reinforced by the Hospital Law which states that every patient has the right to receive care with due respect for his/her dignity as a human being. It is further specified that such care should cover not only the practice of medicine and nursing but also extends to other members of the health profession, accommodation, and administrative or technical services. With regard to privacy, this law grants patients the right to the protection of their private life. This includes the right to expect appropriate and confidential treatment of data, documents and files containing personal information, including observations and medical findings.

Doctors have an absolute obligation to ensure that medical information remains confidential (article 13 (1) of the Code of Medical Ethics) and must observe necessary discretion concerning such information with regard to other healthcare and support personnel. There are exceptions to this rule which are covered in the Greek Penal Code.

3.12.4 End-of-life care and issues

3.12.4.1 Euthanasia/assisted suicide

The Penal Code strictly forbids euthanasia. Article 301 of the Penal Code also carries a sentence of imprisonment for anyone who intentionally convinces a person to commit suicide, regardless of whether the suicide was carried out or even attempted.

3.12.4.2 Non-assistance to a person in danger

Failure to assist a person who is injured or in need of help (or presumably to give treatment in the case of a doctor) would result in prosecution according to article 307 of the penal code for non assistance to a person in danger.

3.12.4.3 Murder at the request of the victim

Article 300 of the Penal Code carries a punishment of imprisonment for anyone who decides upon and carries out manslaughter after a strong and persistent demand on the part of the victim and out of pity for the victim who was suffering from an incurable disease.

3.12.5 Bibliography

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3.13 Hungary

3.13.1 Consent

In the following sections on consent and information, the information is taken from CLIV Act of 1997 on the Healthcare Act.

3.13.1.1 Consent to medical treatment

Except in special cases defined by law, a medical intervention can only be carried out if the patient has given his/her consent based on receipt of the relevant information and without having been misled, threatened or coerced (§ 15 (3)). This can be given orally, in writing or in another form unless stated otherwise in the Healthcare Act. The information shall be individualized.

If a person with incapacity does not have an appointed representative (please see below for details), the right to give or refuse consent and to be informed is given to the patient's legal representative. If he/she does not have one, the right is given to one of the person's relatives in order of importance, as mentioned in § 16 (2) of the same law.

In decisions relating to the treatment of a person who is incapable or has limited capacity, his/her opinions must be considered even if he/she does not have the right to give or refuse consent (§ 16 (5)).

3.13.1.2 Appointment of a healthcare proxy

A person with active legal capacity can appoint another person with active legal capacity to give or refuse consent on his/her behalf. The appointed person must receive the same information as the person would have received. It is also possible for a person with active legal capacity to specify which people should not be granted the right to give or refuse consent or receive information on his/her behalf (e.g. in case of future incapacity).

3.13.1.3 Consent in case of emergency

The consent of a patient with incapacity can be substituted by an expert assessment if obtaining consent from the appointed representative would cause delay. In the case of invasive interventions, the same principle applies with the further condition that any delay would cause serious or permanent harm to the patient's health (§ 17).

3.13.1.4 The right to refuse treatment

3.13.1.4.1 For people with capacity

Everyone has the right to refuse treatment unless doing so would endanger the lives or physical safety of other people. However, if the refusal of treatment is likely to result in serious or permanent harm to the patient's health condition, it must be made in an official or private document "with full authenticity". These documents are regulated in the third Act of 1952 on Civil Procedure.

The right to refuse life-saving or life-sustaining treatment is restricted to patients suffering from a severe disease which, in the opinion of medical science, is likely to cause death in the not too distant future and which even with the appropriate medical treatment is not curable (§ 20). The refusal is only valid if a medical committee examines the patient and reports unanimously in written form that the patient made his/her decision in full awareness of the consequences and that the conditions governing the exercise of this right have been met. The committee is made up of the patient's attending physician, another doctor from the same field not involved in the treatment and a psychiatrist.

Attempts must be made to identify in private conversation the reasons behind the patient's refusal of treatment mentioned in the two previous paragraphs and to try to change it. During this conversation and in addition to the standard requirements for the provision of information, patients must be informed of the consequences of such refusal. They can withdraw their refusal at any time without any formal obligations.

3.13.1.4.2 For people with incapacity

A person with incapacity does not have the right to refuse treatment which is likely to result in serious or permanent harm to his/her health (§ 21.1).

If the patient with diminished or precluded legal capacity refuses life-saving or life-sustaining treatment, the healthcare institution must file an action for consent from the court (i.e. to override the refusal). Until a court judgement has been made, the doctor must continue the treatment. In a direct life threatening situation, consent from the court for the necessary intervention is not required (§ 21(2)).

3.13.1.5 The right to withdraw consent

Consent can be withdrawn at any time. If the patient has no substantial reason for withdrawing consent, he/she may be obliged to cover any justifiable resulting expenses (§ 15(6)).

3.13.1.6 Consent to non-conventional treatment

No special rules are applicable.

3.13.1.7 Consent to the donation of organs and/or human tissue

Written consent is required for the removal, during an intervention, of any living cell, plasma, tissue or organs for use other than that related to the person's treatment. Patients have the right to make arrangements for the use of their body after their death. They can also refuse the post mortem removal of organs and body tissue for use in transplantation or other treatment, as well as for studying and teaching purposes (§ 20). If no statement is made concerning the post-mortem removal of organs, it is presumed that the person consented.

3.13.1.8 Consent to research and clinical trials

Informed consent is required for participation in research activities (European Commission, 2006).

3.13.2 Advance directive

3.13.2.1 The legal status of advance directives

Article 22 covers the right for a person with active legal capacity to make an advance statement of refusal of life-saving and life-sustaining interventions if he or she suffers from an incurable illness and due to this illness is unable to physically take care of him/herself or if the suffering of the patient cannot be alleviated with drugs. The patient can also appoint another person with active legal capacity to refuse life-saving and life-sustaining treatment subject to the same conditions.

3.13.2.2 Conditions surrounding the writing, validity and registering of an advance directive

To write an advance directive, a person must have "full disposing capacity". The advance directive must be in the form of notarial document. In order to be considered valid, a board-certified psychiatrist must have confirmed in a medical opinion, given not more than a month earlier, that the person had made the decision in full awareness of its consequences. If a person is unable to write, the advance directive must be made in the presence of two witnesses who should also sign the document.

3.13.2.3 What an advance directive can cover

An advance directive can cover:

- the refusal of specific forms of treatment;
- life-supporting or life-saving interventions may be refused if the patient suffers from a serious illness which, according to the current state of medical science, will lead to death within a short period of time even with adequate healthcare, and is incurable;
- certain life-supporting or life-saving interventions may be refused if a person has an incurable disease and as a consequence of the disease is unable to care for him/herself physically or suffers pain that cannot be eased with appropriate therapy;
- the refusal to donate organs and human tissue in case of death;
- the appointment of a healthcare proxy in case of subsequent incapacity;
- a statement as to which people should not be given medical information or granted the right to refuse or consent to treatment on the person's behalf. This can be done irrespective of whether a healthcare proxy is appointed.

3.13.2.4 Obligation to comply with instructions contained in an advance directive

For the statement to be valid, a psychiatrist must also have certified no longer than one month ago that the person who made the statement was aware of the possible con-

sequences of it. Refusal of life-sustaining or life-saving treatment in the context of an advance directive does not lead to the automatic referral to a court to contest the decision and should normally result in the treatment being stopped (Hungarian Civil Liberties Union, 2002).

In case of doubt, the patient's personal declaration made previously must be taken into account. In the absence of such a declaration, the patient's consent to the life-supporting or life-saving intervention must be assumed. (§ 23(1))

3.13.2.5 Amending, renewing and cancelling advance directives

Such statements must be renewed every two years. They can be withdrawn at any time regardless of a person's legal capacity.

3.13.2.6 Latest developments regarding advance directives

On 21 September 2009, Members of the Hungarian Parliament voted for a new Civil Code which contains references to advance directives. The President of Hungary vetoed the Civil Code which means that the Parliament has to reconsider and vote again. However, the President's veto was not aimed at eliminating the new rules of legal capacity, even though the process may affect them. According to the current situation, the new Civil Code will come into force in May 2010.

The new Civil Code contains welcome alterations concerning legal capacity and ways to promote decision-making by adults. It overrides the previous rules of precluded legal capacity and general diminished legal capacity. The new act makes it compulsory to state in the court judgement for which issues the person does not have full, but only diminished legal capacity. In addition, the new Civil Code has created rules covering advance directives in which a person with full legal capacity can state their wishes, basically on any kind of civil law issue. Furthermore, the new act introduces rules on supported decision-making, which allows one person to help another in making a decision without this affecting the legal capacity of the latter. The above-mentioned rules can also be combined.

3.13.3 Access to information/diagnosis

3.13.3.1 The right to be informed

Patients are entitled to full and detailed information about their state of health and possible treatment. Article 13 states that patients are entitled to information about:

- their state of health, including its medical evaluation,
- the recommended examinations and interventions,
- the possible benefits and risks of performing or not performing the recommended examinations and interventions,
- the planned dates for performing the examinations and interventions,

- their right to decide in respect of the recommended examination or intervention,
- the possible alternative procedures and methods,
- the course of care and the expected outcome,
- additional services, and
- the recommended lifestyle.

They are also entitled to receive information about the results, possible unsuccessful outcomes or unexpected results (and the reasons for this) during the treatment and after various examinations and interventions.

The patient has a right to ask additional questions when the information is being provided and afterwards.

Information must be provided in a way that is understandable taking into account the age, level of education, knowledge and state of mind of the patient. People with incapacity and those with limited capacity have the right to receive information that corresponds to their age and mental state. Patients who cannot consent also have the right to be informed.

The patient shall have a right to be informed even in cases where his/her consent is not otherwise a condition for initiating medical care. (§ 14 (3))

If the patient's legal capacity is diminished or precluded the attending physician shall also inform the persons mentioned in Article 16 of the Healthcare Act.

3.13.3.2 Access to medical files

The patient's right to become acquainted with the medical record is established in Article 24 of the Healthcare Act. A patient shall have the right to become acquainted with the data contained in his/her medical record and shall have the right to request information about his/her healthcare data.

The healthcare provider shall dispose of the medical record, while the patient shall dispose of the data contained therein.

The patient shall have the right to:

- be informed of the management of the data related to the medical treatment,
- become acquainted with the healthcare data relating to him/her,
- gain access to the medical record and receive copies thereof at his/her own expense,
- be given a discharge summary upon discharge from the healthcare institution,
- receive a written summary or abridged opinion of his/her health data for justified purposes, at his/her own expense.

The right to inspect the medical record of a person with no disposing capacity shall be exercised by a person as defined in paragraphs (1) and (2) of Article 16.

The access to medical records beside the patient is distinctly regulated in the Healthcare Act concerning the state of the medical treatment, if it is in the patient's lifetime or after his/her death and the person who files for access such records.

3.13.3.3 The right to designate another person to be informed on one's behalf

A legally competent patient may waive the right to be informed, except in cases when s/he must be aware of the nature of his/her illness in order not to endanger the health of others. If an intervention takes place at the patient's initiative and not for therapeutic purposes, such waiver of the right to be informed shall only be valid in writing. (§ 14(1))

3.13.3.4 The doctor's right to withhold information

Article 135 states that the attending physician shall be circumspect in informing the patient, and shall do so gradually when necessary, considering the patient's condition and circumstances. This rule might lead to abuse if it is interpreted in as implying that it is not necessary to inform the patient of his/her condition and if circumstances justify not doing so. This depends on the evaluation of the attending physician.

3.13.3.5 The patient's right to refuse information

A legally competent patient may waive the right to be informed, except in cases when s/he must be aware of the nature of his/her illness in order not to endanger the health of others. If an intervention takes place at the patient's initiative and not for therapeutic purposes, such waiver of the right to be informed shall only be valid in writing. (§ 14(1))

3.13.3.6 Confidentiality/disclosure of information to other people

Article 25 of the Healthcare Act covers the right to medical confidentiality. It states that people who are involved in the treatment of a patient should not disclose health and personal information obtained during treatment to other people unless those people have the right to such information and they shall treat it with confidentiality.

The patient also has the right to decide who should and should not have access to this information and may make a statement as to who is to receive information on his/her illness and the expected outcome thereof and who is to be excluded from becoming partially or fully acquainted with his/her healthcare data. (§ 25)

Disclosure of information without the patient's consent is nevertheless possible if specified by law and necessary to protect the life, physical safety and health of other people. According to the Hungarian Civil Liberties Union, a caregiver may be informed against the expressed will of the patient if care is needed in order to ensure that the health of the patient does not deteriorate.

People involved in the patient's healthcare may disclose his/her healthcare and personal data, which they might learn in the course of delivering such care (called 'medical secret'), to those entitled thereto and must ensure that such data is treated with confidentiality.

3.13.4 End-of-life care and issues

3.13.4.1 End-of-life and palliative care

Article 11 paragraph 3 of the Healthcare Law allows for patients who are in a serious condition to be accompanied by a specific person. This could be a person who was appointed to be informed and make healthcare decisions on their behalf (mentioned in § 16). If such a person was not appointed whilst the patient had active legal capacity, this could be the person's legal representative or another person (listed in order of priority in § 16(2)). This right is not limited to end-of-life care but also applies to patients who, due to their medical condition, are physically unable to take care of themselves, whose pain cannot be alleviated with drugs or who are in a condition of psychological crisis.

According to § 23 (2), patients have a right to receive medical care to alleviate their suffering and lessen their pain, even if they have refused life-saving or life-sustaining treatment as permitted by § 20 (3) of the Healthcare Act.

3.13.4.2 Euthanasia

There are currently no initiatives in Hungary to legalise active euthanasia or assisted suicide (European Association for Palliative Care, 2006). The Constitutional Court of Hungary has stated in its ruling of 22/2003 that the current regulation on the refusal of treatment is not against the Constitution.

Passive euthanasia is legal in Hungary (please see the section on the right to refuse treatment) but advance directives for the refusal of treatment and active euthanasia are completely different matters.

3.13.4.3 Assisted suicide

Article 168 of the Criminal Code states that it is a crime for a person to persuade somebody else to commit suicide or to help them to commit suicide and that a person who commits this crime may be punished by up to five years' imprisonment.

3.13.4.4 Murder

According to Article 166 of the Criminal Code, it is a crime to take the life of another person. The sentence for this crime is between 5 and 15 years' imprisonment.

3.13.5 Bibliography

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3.14 Iceland

3.14.1 Consent

3.14.1.1 Consent to medical treatment

Article 7 of the Act on the Rights of Patients, No. 74 /1997 deals with consent to treatment:

"The right of the patient to decide whether s/he will accept treatment shall be respected. The provisions of the Legal Majority Act apply to the consent to treatment of patients who, on account of lack of intelligence or for other reasons provided for by that Act, are incapable of making a decision regarding treatment. In such cases the patient shall nevertheless be consulted to the extent possible. Without prejudice to Article 9, no treatment may be given without the prior consent of the patient, cf. paragraphs 1 and 2. The consent shall be in writing whenever possible and indicate the information the patient has been provided with and that he has understood the information."

3.14.1.2 Consent in case of emergency

Consent can be presumed if a patient is unconscious or unable to express his/her will and urgent treatment is needed, unless it is known with certainty that he/she would have refused to accept treatment (article 9).

3.14.1.3 Refusal and withdrawal of consent

Article 8 of the Act on the Rights of Patients, No. 74/1997 deals with refusal and withdrawal of consent:

"If the patient refuses to accept treatment, a doctor shall inform him/her about the possible consequences of his/her decision. The patient may discontinue treatment at any time, without prejudice to other laws. If the patient refuses to accept treatment, his/her doctor or the health worker supervising the treatment shall inform him/her of the possible consequences of his/her decision. (.../...) The decision of a patient to refuse to accept or to discontinue treatment shall be recorded in his/her clinical record and it shall be confirmed that s/he has received information on the possible consequences of his/her decision."

3.14.1.4 Consent to the donation of organs and/or human tissue

The Directorate of Health issues organ donation cards which people can fill in at their discretion and which authorize the removal of organs or other biological materials after death. However, it is not clear what the situation would be for people who do not carry such a card.

3.14.1.5 Consent to participation in the training and instruction of students

Article 11 states a patient must be informed if students are to be present during his/her treatment and he/she has the right to refuse to take part in such training and instruction.

3.14.1.6 Consent to research

Article 10 of the Act on the Rights of Patients, No. 74/1997 sets conditions for the participation of patients in scientific research. It states:

"A patient shall give his formal consent prior to participation in scientific research. Before such consent is given detailed information shall be provided on the scientific research, the possible risks and benefits involved and what the participation entails. It shall be explained to the patient that he can refuse to participate in scientific research and that he can cease participation at any time after it has commenced. The provisions of Article 15 apply to access to information contained in clinical records, including biological samples, for the purposes of scientific research. It is prohibited to conduct scientific research on a patient which does not fulfill the conditions of Article 2 (4)."

The above paragraph is reproduced in Regulation No. 552/1999 on Scientific Research in the Health Sector, with the addition of a further statement, i.e. that the information shall be given in such a manner that the participant can understand it. Article 4 of this regulation states that the interests of the individual shall invariably be given priority over the interests of science or of society as a whole.

Although there is no specific reference to the participation of people lacking legal competence in scientific research in the Act or the Regulation, the latter outlines the role of ethics committees and the National Bioethics Committee in evaluating project proposals and deciding whether there are any scientific and/or ethical grounds to oppose proposed studies.

Please also see section on confidentiality/disclosure of information to other people.

3.14.2 Advance directives

It is stated on the website of the Prime Minister's Office that by signing a living will, individuals can influence decisions that will be made regarding treatment at the end of their lives, and thus free their closest relatives from the burden of making decisions. However, it is not clear whether such advance directives have legal status.

3.14.3 Access to information/diagnosis

3.14.3.1 The right to be informed

Chapter II of the Act on the Rights of Patients of 1997 deals with information and consent. Article 5 states:

"A patient has the right to obtain information regarding:

- a. his/her state of health, including medical information on his condition and prognosis,*
- b. the proposed treatment, as well as information on its course, risks and benefits,*

c. possible remedies other than the proposed treatment and the consequences of lack of treatment,

d. the possibility of seeking the opinion of another doctor or other health workers, as appropriate, regarding treatment, condition and prognosis."

This information must be provided whenever there is reason to do so and in such a way and under such circumstances that the patient can understand it. It must be entered in the clinical record of the patient that s/he has received this information. According article 6, if the patient is unable to handle the information provided, it must be given to a close relative or the patient's legal guardian.

3.14.3.2 Access to medical files

According to article 14 of the Act on the Rights of Patients, No. 74/1997, a doctor or another person who maintains a patient's clinical record is obliged to show it to the patient (or to his/her agent), in full or in part, and to give them a copy if they so request. If the information in the clinical record is considered wrong or misleading by the patient or by his/her agent, they are entitled to make comments which must be attached to the record. A charge may be made for the copy (according to article 12 of the Information Act).

If there is information in the medical file which has been provided by someone other than the patient or a health worker, it cannot be shown to the patient without the approval of the person who provided it. If that person is no longer available (e.g. he/she has died, cannot be found or refuses to consent to the disclosure), the file must be sent to the Directorate General of Public Health. The latter must decide within eight weeks whether the patient or his/her agent can have access to the information in question (article 14 of Law No. 74/1997).

3.14.3.3 The right to designate another person to be informed on one's behalf

Please see below

3.14.3.4 The doctor's right to withhold information

The right to withhold information from the patient is covered by article 6 of the above-mentioned law. Two justifiable reasons are given.

The first is that the patient asked not to be informed. In this case, the patient can appoint another person to receive the information on his/her behalf. Details of the refusal of information and/or the appointment of another person must be entered in the patient's clinical record, including the actual identity of the person appointed to receive information.

The second is that the patient is unable to master the information provided. In this case, the information can be given to a close relative or legal guardian if one has been appointed.

3.14.3.5 The patient's right to refuse information

As stated above, this is covered by article 6 of the Act on the Rights of Patients, No. 74/1997.

3.14.3.6 Confidentiality/disclosure of information to other people

Confidentiality and professional secrecy is dealt with in Article 12, Chapter III of the Act on the Rights of Patients of 1997:

A health worker shall fully respect the principle of professional secrecy regarding whatever s/he comes across in the course of his or her work regarding the health, condition, diagnosis, prognosis and treatment of a patient, as well as other personal information. Professional secrecy continues to apply after the death of a patient and after the worker has left his/her job. The worker may provide information for urgent reasons, with due regard to the wishes of the deceased and the interests of those concerned. When a worker is in doubt, s/he can seek the opinion of the Directorate General of Public Health.

Data can be taken from the medical file and used for the purposes of research provided that whenever this occurs all the conditions (mentioned in article 2, § 4) for scientific research have been fulfilled and that such access is recorded in the file (article 15).

3.14.4 End-of-life care and issues

3.14.4.1 Easing of suffering and the presence of other people

Article 23 of the Act on the Rights of Patients, No. 74/1997 states that a patient's suffering must be eased to the best of current ability. Patients have the right to receive support from family, relatives and friends during their treatment and stay. Furthermore, patients and their closest relatives have the right to spiritual, social and religious support. It is not stated in the Act that these provisions are limited to end-of-life treatment, although it is clear that they would also apply to such treatment.

3.14.4.2 The termination of treatment

Article 24 of the same act specifically refers to the treatment of dying patients:

"A patient has the right to die with dignity. If a dying patient expresses clearly that s/he declines further life-prolonging treatment, or resuscitation efforts, his/her doctor must respect his/her decision. If a dying patient is mentally or physically too ill to decide on his/her treatment, the doctor shall endeavour to consult the relatives of the patient and his/her colleagues before s/he decides on the continuation or termination of treatment."

3.14.4.3 Euthanasia

According to the European Association of Palliative Care (2006),

"At the current time, there are no initiatives in Iceland that seek the legalization of euthanasia or assisted suicide. The discussion on euthanasia has never received any interest in Iceland, and both lay people and healthcare professionals seem to have

little interest in the topic. A few articles have appeared in newspapers but gained little attention."

The following extract, taken from Chapter XXIII of the Penal Code on Manslaughter and Bodily Injuries, may have some relevance to the issue of euthanasia and assisted suicide.

3.14.4.4 Assisted suicide

Art. 214 of the Penal Code: In case a person be conducive to another person's committing suicide, he/she shall be subject to [imprisonment for up to 1 year] or fines. If this is done for a selfish purpose the penalty shall be imprisonment for up to 3 years.

3.14.4.5 Non-assistance to a person in danger

Art. 221 of the Penal Code: Should a person fail to come to the assistance of another whose life is endangered although he/she could do so without endangering his/her life or health or that of others, this will be subject to imprisonment for up to 2 years or fines in case of mitigating circumstances.

3.14.4.6 Murder

Art. 211 of the Penal Code: Anyone who takes the life of another person shall be subject to imprisonment for no less than 5 years or for life.

Art. 213 of the Penal Code: Anyone who takes the life of another person at his/her urgent request shall be subject to imprisonment for up to 3 years.

3.14.5 Bibliography

European Association of Palliative Care (2006), EAPC Task Force on the Development of Palliative Care in Europe – Iceland: <http://www.eapcnet.org/download/forPolicy/CountriesRep/Iceland.pdf>

3.15 Ireland

3.15.1 Consent

3.15.1.1 Consent to medical treatment

In Ireland, although the term “informed consent” is frequently used in the medical and/or legal context, there is no Irish judicial or statutory definition of this term (Tomkin and Hanafin, 1995) (other than in the context of the Mental Health Act 2001). If a doctor either intentionally or recklessly touches a patient, in the absence of legally effective consent, he/she could be accused of assault. Such consent must be freely given, without any coercion or pressure. This forms the basic framework of the doctor-patient relationship.

Under common law, it is illegal to give treatment to a person who has not consented to it, unless the treatment is of an urgent nature.

3.15.1.2 Consent to treatment under the Mental Health Act

Part 4 of the Mental Health Act 2001 defines consent in relation to a patient under the Act as meaning consent obtained freely without threats or inducements where the consultant psychiatrist responsible for the care and treatment of the patient is satisfied that the patient is capable of understanding the nature purpose and likely effects of the proposed treatment and has given the patient adequate information in a form and language that the patient can understand on the nature purpose and likely effects (section 56).

Consent of the patient is not required for treatment when in the opinion of the consultant psychiatrist responsible for their care, the treatment is necessary to safeguard the life of the patient, to restore their health, alleviate their condition, or relieve their suffering and by reason of their mental disorder the patient is incapable of giving such consent. In all other circumstances consent is required. (section 57).

There are further safeguards in relation to certain highly invasive treatments. Psycho-surgery, even with the written consent of the patient, must be authorised by a Tribunal. Electroconvulsive therapy requires either the written consent of the patient or the approval of the consultant psychiatrist responsible for the patient and a second consultant psychiatrist and must be administered in accordance with the rules published by the Mental Health Commission (section 58-59).

Medication for a mental disorder cannot be continued for more than three months unless the patient consents in writing or if the patient is unable or unwilling to consent, with the approval of the consultant psychiatrist responsible and a second consultant psychiatrist. Consent or approval must be obtained every further three months that the medication is continued (section 60).

3.15.1.3 Consent in case of emergency

Under common law, it is illegal to give treatment to a person who has not consented to it, unless the treatment is of an urgent nature.

3.15.1.4 Consent to the donation of organs and/or human tissue

People may indicate by means of an organ donation card that they wish to donate one or several organs in the event of their death. In practice, a person's next of kin may be asked for consent to remove the organs of a deceased person and a refusal by the next of kin is not contested. Whilst the law is not clear on this issue, it seems that the next of kin are not obliged to respect the wishes of the deceased person (Citizens Information Board, 2009). Moreover, children and mentally incapacitated adults do not have the right to consent to body or organ donation.

In 2008, the Human Body Organs and Human Tissue Bill (a private members bill) was introduced in the Seanad by Senator Feargal Quinn. The bill promotes the introduction of provisions for presumed consent, sometimes known as an "opt out" system (Prendeville, 2008).

3.15.1.5 Consent to clinical trials

The Control of Clinical Trials Act of 1987 (which came into force on 6 December 1988) addresses the issue of participation in clinical drug trials. This legislation compels clinical trials to be approved by the Minister for Health and an Ethics Committee. Anyone who carries out clinical trials without abiding by the rules of this Act would be considered to have committed a criminal offence.

Participants in clinical trials must give informed consent. Nevertheless, a person who lacks mental capacity can take part in such trials provided that someone has given written and signed consent on his/her behalf. This must be an independent person who has been judged competent to make such a decision by the ethics committee. It cannot be anyone who applied to undertake the trials or is involved in conducting it.

Anyone who is a patient with a mental disorder in an approved centre under the Mental Health Act 2001 cannot take part in a clinical trial (section 70).

3.15.2 Advanced directives/living wills

In Ireland, advance directives are not legally binding, although a growing number of people are in fact writing them. According to Costello (1998), in a recent Ward of Court case, certain comments were made by the members of the Supreme Court to the effect that views expressed by a person in relation to future medical treatment (which could have been written in an advance directive) would be taken into account by the Court in coming to decisions in relation to the termination of treatment. Nevertheless, the extent that such directives would be binding to medical professionals remains unclear.

In July 2008, the Law Reform Commission published the Consultation Paper on Bioethics: Advance Care Directives (LRC CP 51-2008) (3rd Programme of Law Reform, Project 30). The Consultation Paper provisionally recommends that there is a need for legislation to cater for people who make advance care directives, whether verbally or in writing. An advance care directive sets out a person's wishes about what should happen to them in the event of an incapacitating accident (such as a serious car crash) or illness (such as stroke or the onset of Alzheimer's disease) that makes it impossible for them to communicate their wishes directly. The main recommendations in the Consultation Paper are that: the proposed legislation would not involve euthanasia, assisted suicide or allow a person to refuse basic care; it would deal only with advance care directives involving refusal of treatment, for example: "I do not wish to be resuscitated;" an advance care directive could, in general, be written or verbal but one that refuses life-sustaining treatment would have to be in writing; the proposed legislation could, in general, allow a person to refuse treatment on religious grounds; a person should be encouraged to seek medical advice when making an advance care directive, but it should only be mandatory in the case of directives involving the refusal of life-sustaining treatment. The Commission intends to publish a Report on this area by the end of 2009.

3.15.3 Access to information/diagnosis

3.15.3.1 The right to be informed

Under common law consent must be based on an understanding of the nature of proposed treatment, likely effects and risks of the treatment, the likelihood of success and details of any alternative treatment possible. The more a patient is capable of understanding, the more detailed the explanation should be and vice versa.

3.15.3.2 Access to medical files

The Freedom of Information (Fol) Act 1997 covers the issue of access to information. According to this act, all patients (treated under the public health system) have the right to access their health records. Previously, the only legislation relating to access to information concerned that which was held on computer and hence came under data protection laws (Cusack, 1998). Under the Fol access to records covers information in any form which relates to medical, psychiatric and psychological treatment or care and may include opinions made about patients on this basis.

Requests for access to records should be made in writing to the head of the relevant public body (the Chief Executive Officer). This is radically different from the previous system, whereby it was the responsibility of the doctor to decide on access to records. Not later than four weeks after receipt of a request, the CEO must decide whether or not to grant access to the information and determine how access will be arranged. In the case of a favourable response (wholly or in part), the requester should be notified of this, provided with details of when the request was granted and the name of the person dealing with the request and details of any fee to be charged. In the case of a negative response (wholly or in part), the requester should be informed of the reasons.

If access to a record is granted, the request can be provided in a number of ways, e.g. a copy of the record, a transcript of the information concerned, a computer disk or other electronic device, the opportunity to inspect the record, written notes of shorthand or coded information or a combination of these forms.

3.15.3.3 The doctor's right to withhold information

Access to information can be denied for various reasons. Access can be refused if in the opinion of the CEO the information might be prejudicial to the mental health, well-being or emotional condition of the person making the request. However, in such cases the patient would still be able to access the required records, but through the intermediary of a health professional which he/she had specified (e.g. a doctor, dentist or other kind of health worker).

3.15.3.4 Confidentiality/disclosure of information to other people

According to the Irish Code of Medical Ethics, confidentiality is a fundamental aspect of the doctor/patient relationship. The FoI of 1997 has been described as an important step forward with regard to patient confidentiality (Cusack, 1998). According to this act any request for information will be refused unless the information relates to the person requesting it and that person has either consented to its disclosure or failure to disclose the information would entail a serious and imminent danger to the life or health of an individual.

3.15.4 End-of-life care and issues

3.15.4.1 Euthanasia

Concerning passive euthanasia, whilst there is no law which deals directly with the issue of refusal of life-sustaining treatment, it has been claimed that such a right may be covered by article 40.3.1. of the Constitution of Ireland (1937):

"The State guarantees in its laws to respect, and, as far as practicable, by its laws to defend and vindicate the personal rights of the citizen."

This article has been interpreted in a number of ways. According to Judge Costello (1986), "the dignity and autonomy of the human person require the State to recognise that decisions relating to life and death are, generally speaking, ones which a competent adult should be free to make without outside restraint and that this freedom should be regarded as an aspect of the right to privacy which should be protected as a "personal" right by Article 40.3.1." He also stated that in the case of incompetent patients, the proper discharge of the duty of care would involve no legal fault. According to this line of thought, the foregoing or withholding of life-sustaining treatment for terminally ill patients does not involve a crime and is compatible with the Constitution.

Active euthanasia, on the other hand, is considered by the Medical Council as professional misconduct. It is also a crime and is classed as murder. Nevertheless, a doctor can legally administer drugs in order to reduce the suffering of a patient even if there is a risk

that the dose necessary to relieve suffering could kill the patient. This is known as "double effect" and is not a crime as the doctor's intention is to ease pain, not to kill.

3.15.4.2 Assisted suicide

In the past suicide was considered as a crime under common law. This changed in 1993 due to the Criminal Law (Suicide) Act which stated that suicide was no longer to be considered an offence. However, assisted suicide is a crime. According to § 2(2) of this Act, any person who aids, abets or procures the suicide or attempted suicide of another, is liable to a prison sentence of up to fourteen years (Tomkin and Hanafin, 1995). Physician assisted suicide would also be a crime.

3.15.5 Bibliography

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3.16 Italy

3.16.1 Consent

3.16.1.1 Consent to treatment

Consent to medical treatment is covered by article 32 (2) of the Italian Constitution, which states,

"No-one may be forced to undergo any particular medical treatment, save under the provisions of the law. In no case shall the law violate the limits imposed by proper respect for the human person."

Article 13 (1) of the Constitution states that personal liberty is inviolable. As a person's moral liberty, the right to self-determination and physical liberty (the right to respect for bodily integrity) are all elements of personal liberty, this article can also be understood to cover the issue of consent. Article 32 of the Constitution further states that nobody may be forcefully submitted to medical treatment except as regulated by law and that such law may in no case violate the limits imposed by respect for the human being.

Consent is also covered by the Italian Code of Medical Ethics of 18.12.2006. Articles 33 to 37 deal specifically with informed consent. The doctor cannot undertake any diagnostic or therapeutic procedure without the informed consent of the patient. The doctor's actions must be guided by the will of the patient which should be freely and explicitly expressed. This should be supplemented by written consent. Diagnostic or therapeutic procedures which could be seriously hazardous to the safety of the patient, can only be undertaken in the case of extreme necessity. The doctor must explain the possible consequences of the proposed procedures and obtain documented and informed consent.

Article 37 provides for the situation where a person may be unable to consent due to infirmity of the mind. In this case, the person's legal representative can consent on his/her behalf.

3.16.1.2 Consent in case of emergency

If the legal representative opposes treatment which the doctor considers to be essential and urgent, the doctor must inform the judicial authorities. Such opposition is ineffective in cases where the law provides for compulsory medical treatment. If treatment is necessary and urgent and the patient is unable at that particular moment to object to it, the doctor can provide any essential treatment and care (article 37).

3.16.1.3 The right to refuse treatment

If a patient who is capable of comprehension and intention explicitly refuses treatment, the doctor cannot go ahead with any diagnostic or curative action.

3.16.1.4 Consent to the donation of organs and/or human tissue

Organ donation from living donors can only be carried out if both the donor and the person receiving the organ fully understand the risks involved and freely consent to the operation. This is covered by article 41 of the Italian Code of Medical Ethics.

3.16.1.5 Consent to clinical trials and research

The consent of the patient is obligatory for pharmaceutical experimentation according to the Legislative Decree of 24.6.2003, n. 211, for the implementation of the Direction 2001/20/CE concerning the carrying on of the suitable clinic treatments for clinical experimentation of new medicinal preparations. The patient must also have received the necessary information in order to make a decision, and he/she can withdraw consent at any moment.

A person who is unable to give his/her consent can only participate in research under special conditions including, amongst others:

- That his/her legal representative has given his/her consent after getting the necessary information; the consent must represent the alleged will of the person cared for and it can be withdrawn at any moment, without any prejudice for the incapable person;
- That the incapable person has received all the relevant information necessary to understand either the kind of experimentation which is going to be carried on or the subsequent risks and benefits;
- That the experimentation is essential to validate results already obtained in clinical experimentation on people who are able to give their informed consent or to validate the results of different research methods on the condition that the experimentation is strictly related to a life threatening clinical situation or of a disabling clinical condition that the person who is unable to consent is affected by.

Pharmaceutical experimentation is also covered by articles 48 and 49 of the Italian Code of Medical Ethics.

3.16.2 Advance directives

There is not yet a law about advance directives in Italy. Whilst waiting for a clear and appropriate law, it is nevertheless possible in Italy to have recourse to a rule which allows for the wishes of an incapable person to be respected.

Art. 408 of the civil code as renewed by law n. 6/2004 grants the possibility to incapable people to appoint, directly and prior to their illness, the guardian they would like in the future. This involves planning and preparing for possible future incapacity. The appointing deed must be made by a legal notary or written in private and then authenticated. The guardian's duties can be specified in the deed either with regard to the handling of the person's properties or to matters concerning decisions related to certain treatments or therapies.

The anticipated appointment of one's guardian can therefore establish choices linked to healthcare (beginning from his/her consent to hospitalization to decisions about the continuation of treatment, medical research and all the other related matters).

Previously expressed wishes are also covered in article 38 of the Italian Code of Medical Ethics which states that the doctor must respect the freely expressed wishes of the patient and act in respect of the patient's dignity, freedom and autonomy. This, it is stated, includes respecting the previously expressed wishes of the patient who is no longer able to express him/herself, provided that these wishes were clearly expressed and documented.

3.16.3 Access to information/diagnosis

3.16.3.1 Access to information

The right to be informed of one's diagnosis and state of health is covered by the Italian Code of Medical Ethics. According to article 33, the doctor must provide the patient with clear and appropriate information on the diagnosis, prognosis, prospective treatment and the likely consequences of treatment or non-treatment. If the patient has additional questions, these must also be answered. If the information to be given includes a serious or fatal prognosis or something which is likely to cause anxiety or suffering to the patient, it must be provided with circumspection, using terminology which is unlikely to traumatisate the patient, making sure to include any element of optimism.

The doctor must take into account the particularities of each patient to whom he or she gives information. This includes the patient's level of education, emotionality and reasoning capacity. He/she must further ensure that information about diagnostic and therapeutic procedures is limited to what the patient is capable of receiving and accepting in view of his/her education and psychological condition. Superfluous details associated with scientific aspects should be avoided.

3.16.3.2 Access to medical records

The doctor must grant access to the patient's medical records in his/her possession to the patient's legal representative or to doctors or institutions indicated by the patient in writing (article 25).

3.16.3.3 The right to appoint another person to be informed on one's behalf

The documented wish of the patient to delegate another person to be informed on his/her behalf must be respected (article 33).

3.16.3.4 The doctor's right to withhold information

As mentioned above (article 33 of the Code of Medical Ethics), the doctor may be justified in withholding certain information.

The procedure for informing the patient is very detailed and could adapt well to a person with dementia, although the valid safeguards against traumatising the patient could also clearly be used to justify a paternalistic attitude.

3.16.3.5 The patient's right to refuse information

The documented wish of the patient not to be informed (or, as mentioned above, to delegate another person to be informed on his/her behalf) must be respected (article 33).

3.16.3.6 Confidentiality/disclosure of information to other people

According to article 34 of the Italian Code of Medical Ethics information can be provided to a spouse provided that the patient consents to this. In the event of grave danger to the health or life of any third party information can be given without consent.

It is not stated that information can be given to guardians. However, article 37 stipulates that where a patient is afflicted by infirmity of mind, informed consent must be given by the legal representative. As informed consent is dependent on the person making the decision being fully aware of all the relevant factors, this article implies that legal guardians have the same right to information as the patient.

3.16.4 End-of-life care and issues

3.16.4.1 Palliative care

According to art 39 of the Italian Code of Medical Ethics relating to caring for incurable people:

"In the event of a disease with a poor prognosis or which has reached the terminal stage, the physician should behave in such a way as to prevent unnecessary physical and mental suffering to the patient and provide the appropriate treatment to protect, as far as possible, the quality of life and the dignity of the patient. In case of a reduced state of consciousness, the doctor should continue to administer life-supporting treatment for as long as he/she deems it worthwhile, avoiding any form of harsh and futile treatment."

There is at the moment no specific law on palliative care. However, there is an advanced bill currently being debated in Parliament.

3.16.4.2 Euthanasia

Passive euthanasia, which involves the withholding of life-preserving measures, is illegal and could be considered as "incitement or assisted suicide" under article 580 of the Penal Code:

"Whoever leads or incites another person to commit suicide, or assists them in any way, shall be punished, if suicide occurs, by imprisonment of between five and twelve years..."

According to article 579 of the Penal Code, direct active euthanasia is considered as homicide.

3.16.4.3 Assisted suicide

Please see the above section and the one on "murder at the request of the victim."

3.16.4.4 Non-assistance to a person in danger

Non-assistance to a person who is or appears to be unconscious, wounded or otherwise in danger, or failure to inform the relevant authorities may be punished by a prison sentence of up to 3 months or a fine. The sentence is increased if the person suffers injury as a result and is doubled in case of death (article 593 of the Penal Code).

3.16.4.5 Murder

Article 575 of the Penal Code states that whoever kills another person will be sentenced to a minimum of 21 years in prison. Articles 576 to 577 mention certain aggravating circumstances which may lead to a more severe sentence such as life imprisonment or even the death penalty. These include, amongst other things, premedication or the fact that the victim is a close relation. Article 584 mentions a lower sentence of 10 to 18 years if someone kills another person but did not intend to do so.

3.16.4.6 Murder at the request of the victim

Article 579 of the Penal Code states that whoever causes someone's death, with his/her consent, shall be punished by imprisonment of between six and fifteen years.

3.17 Latvia

3.17.1 Consent

3.17.1.1 Consent to medical treatment

In Chapter VI of the Medical Treatment Law of 1997, the emphasis is on the doctor's obligation to obtain the patient's consent. According to section 41, a doctor must obtain the consent of the patient for medical treatment.

Article 70 states that a written request by the guardian or his or her approval must be obtained for mental treatment for people who are deemed not to be of active capacity (except in the case of compulsory treatment).

3.17.1.2 Consent in case of emergency treatment

Section 49 of the Medical Treatment Law deals with cases where a delay might endanger the life of the patient and it is impossible to obtain the consent of family members, closest relatives or lawful representatives. In such cases, medical professionals have a duty to take emergency measures within the scope of their competence. If there is enough time, they should get the examination and treatment plan approved and let a doctor's council taken the necessary decision.

3.17.1.3 The right to refuse treatment

Section 23 of the Medical Treatment Law of 1997 concentrates on the patient's right to refuse treatment. It states:

A patient has the right to refuse, in full or in part, examination or medical treatment offered by certifying such refusal with his or her signature. If a patient is a minor or a person who due to his or her state of health is unable to understand the consequences of his or her actions, family members, but if such do not exist, the closest relatives or lawful representatives of the patient (trustees, guardians) have such rights and liability for the decisions taken. The doctor has a duty to explain to the patient, his or her family members, closest relatives or lawful representatives (trustees, guardians) the consequences of such refusal. If the person has accepted a treatment plan, he or she is responsible for observing all instructions of the medical practitioner related to the medical treatment and care.

3.17.1.4 Consent to participation in research

Informed consent is required for participation in research activities (European Commission, 2006).

3.17.2 Access to information/diagnosis

3.17.2.1 Access to information

According to section 20 of the Medical Treatment Law, "Patients have the right to receive information from a doctor in a way that they can comprehend regarding the diagnosis of

their illness, examination and medical treatment plan, as well as regarding other medical treatment methods and the prognosis."

Section 41, which deals with the doctor's obligation to obtain the patient's consent, further stipulates that the doctor has a duty to provide information to the patient in a comprehensive way regarding the diagnosis of the illness, the planned examination and medical treatment, as well as regarding other medical treatment methods and prognosis. The doctor has a duty to explain and inform the patient of the possible effects and complications of the disease, as well as providing information about possible side effects of the prescribed medical substances or medical treatment methods.

3.17.2.2 The doctor's right to withhold information

Section 41 of the Medical Treatment Law also permits the doctor to provide incomplete information to the patient regarding the diagnosis and prognosis of the disease if he or she considers that such information may cause deterioration of the state of health of the patient.

3.17.2.3 Confidentiality/disclosure of information to other people

According to section 145 of the Criminal Law, it is an offence to intentionally disclose personal confidential information about another person which was entrusted or communicated to the offender as a result of his/her position or employment. The sentence for such an offence is custodial arrest, community service or a fine not exceeding twenty times the minimum monthly wage.

The obligation to respect confidentiality can also be found in section 50 of the Medical Treatment Law of 1997. This covers both medical information (e.g. the diagnosis and prognosis) and information about the private life of the patient and of his/her close relatives.

Section 50 of the Medical Treatment Law also states that information regarding a patient may be used in scientific research if the anonymity of the patient is guaranteed or his or her consent has been received.

3.17.3 End-of-life care and issues

3.17.3.1 Euthanasia

The Alpha & Omega Society is established as a non-governmental organisation proposing the legalisation of euthanasia or medically-assisted suicide (EAPC Palliative Care Euro-Barometer 2005). According to the Ministry of Justice, there have not been any court cases linked to euthanasia yet (Council of Europe, 2003)

3.17.3.2 Assisted suicide

Section 124 of the Criminal Code addresses the issue of assisted suicide. It states that a person who causes another person to commit or attempt suicide by cruel treatment or

systematic demeaning of his or her personal dignity shall be sentenced to deprivation of liberty for a term of up to three or five years (depending on whether the person was financially or in some other way dependent on him/her).

It is not clear what the sentence would be in case of assisted suicide without cruel treatment or systematic demeaning of the other person.

3.17.3.3 Murder

According to section 116 of the Criminal Code (Chapter XII):

For a person who commits intentional illegal homicide (murder) of another person, the applicable sentence is deprivation of liberty for a term of not less than five years and not exceeding fifteen years, with or without police supervision for a term not exceeding three years.

The sentence is longer if there are aggravating circumstances e.g. the offender knew that the person was in a state of helplessness (section 117). The sentence is shorter if the homicide was committed through negligence (section 123).

3.17.4 Bibliography

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3.18 Lithuania

3.18.1 Consent

3.18.1.1 Consent to medical treatment

Article 8 (the right to refuse treatment) of the Law on the Rights of Patients and Compensation of the Damage to their Health of 1996 (RPCDH) states that patients may not be treated or provided with any other health or nursing care against their will, unless otherwise established by the laws of the Republic of Lithuania. If the possibility exists, patients must be offered other treatment or other healthcare services (§ 1).

§ 4 of the same article states that „the Law on Mental Healthcare shall establish the nature of treatment of a patient, mental patient, who is unable to correctly assess the condition of his/her own health.”

3.18.1.2 Consent to treatment in case of incapacity

Article 6.744 (3) covers consent to treatment in cases where a patient lacks the necessary capacity to consent and does not have a curator or guardian. In such cases, there is a hierarchy of people authorised to consent on the person's behalf: first, the person authorised in writing by the patient with incapacity to act on his/her behalf, second, the spouse or partner. If the spouse or partner is not available or refuses to consent, the obligation goes to a parent or child unless they refuse.

3.18.1.3 Consent in case of emergency

§ 3 allows for patients to be treated without their consent in case of emergency. It states that vital (first or urgent) medical assistance can be given to a patient who is unconscious or whose will is not known for another reason without his/her consent if there is a serious threat to his/her life. Article 8 (5) of the RPCDH states that healthcare services can be provided with the consent of a person's legal representative if the latter cannot be contacted in time and immediate action must be taken in order to save the patient's life (Nys et al., 2007).

3.18.1.4 The right to refuse treatment

Paragraphs 5 and 6 of article 1 of the Law on the Rights of Patients and Compensation of the Damage to their Health of 1996 (RPCDH) address the issue of refusal of treatment by legal representatives. It is not stated whether this is referring to legal representatives of incapable adults or just minors. The paragraphs are as follows:

§ 5. In the course of providing required (first aid or urgent) medical assistance, which requires the consent of the legal representative of the patient, such may be provided also without the legal representative's consent, if this can not be obtained in time or if the legal representative refuses to give his consent, while according to the treating physician or nursing staff member, the rendering of medical assistance is in keeping with the interests of the patient. The case history of the illness of the patient must include a record of this.

§ 6. Should the legal representative of a patient refuse to give his consent for treatment, which is not urgent and the treating physician be of the opinion that the treatment being provided is in keeping with the interests of the patient, the medical commission of the healthcare institution or the Committee for Medical Ethics of Lithuania, has the right to give consent for such treatment. The administration of the healthcare institution or the treating physician shall have the right to appeal to this commission or committee.

3.18.1.5 The right to withdraw consent

Article 8 (4) further states that patients have the right to withdraw consent in written form at any time. Article 6.739 (2) of the Civil Codes grants patients the right to “terminate the contract at any time” and no formal requirements are mentioned.

3.18.1.6 Consent to the donation of organs and/or human tissue

Article 6.746 states,

“Human tissues and organs taken from an anonymous person during the provision of personal healthcare services may be used in cases and pursuant to the procedure prescribed by laws.”

3.18.1.7 Consent to research and clinical trials

The Law on Ethics of Biomedical Research of 11 May 2000 states that biomedical research can only be carried out on people who have given their free and informed consent (article 6). The law also contains a list of vulnerable subjects which includes people with mental disorders who are nevertheless able to give their consent to take part in biomedical research as well as people living in nursing homes. Article 7 of this law sets conditions which must be met before such research can be carried out i.e.

1. it can only be carried out on vulnerable people,
2. the results have the potential to produce real and direct benefit to the health of the research subjects,
3. it does not pose a risk to the health or life of the research subject.

Furthermore, the free and informed consent of the research subject must be attested by 2 witnesses and the head of a healthcare establishment where biomedical research is being conducted. The approval of the Medical Ethics Commission must also be obtained.

Article 7 of the Law on the Rights of Patients and Compensation of the Damage to their Health of 1996 states that people cannot be used for training or scientific or medical experiments without their consent.

3.18.2 Advance directives

There are no legal provisions relating to previously expressed wishes in Lithuania (Nys et al., 2007).

However, according to the Law on Human Death and Critical Care, a person should not be resuscitated if he/she has expressed a wish to this effect and provided that there is approval from a doctors' committee (Council of Europe, 2003).

3.18.3 Access to information/diagnosis

Article 6 of the Law on the Rights of Patients and Compensation of the Damage to their Health of 1996 (RPCDH) deals with the right to information. Information is also contained in section 2 of the Civil Code.

3.18.3.1 The right to be informed

The following paragraph deals with the patient's right to be informed about his/her state of health:

§ 4. The patient shall have a right to information on the condition of his/her health, disease diagnosis, medical examination results, treatment methods and treatment prognosis. The information must be supplied to the patient in a form comprehensible to him/her, with an explanation of the special medical terms involved. In providing information regarding the treatment, the physician must explain to the patient the course of treatment, possible results of the treatment, possible alternative methods of treatment and other circumstances, which may have an effect upon the patient's decision to accept or refuse the proposed treatment. The information should not be supplied to the patient against his/her will, however, his/her will must be clearly expressed and the history of his illness should contain a mention of this wish of his/hers.

§ 9 further specifies that a patient has the right to learn of the specialist's opinion concerning the condition of his/her health and the proposed treatment.

According to article 727 of the Civil Code healthcare providers are obliged to provide patients with information in a form that is comprehensible to the latter, explaining special medical terms used, outlining possible treatment methods, prognosis of treatment and other circumstances which might effect the patient's decision whether or not to consent to the proposed treatment, as well as the likely effects of refusing the proposed treatment.

3.18.3.2 Access to medical files

§ 6 of the RPCDH covers the patients right to access their medical files. It states:

The patient shall have the right to request that copies of the case history of his disease and (or) of other documents, be made at his expense. This right of the patient may only be limited by the procedure established by the laws of the Republic of Lithuania. The physician must explain the significance of the notes included in the case history of his illness. If the patient's request is justified, the physician must correct, complete, remove, explain and (or) change inaccurate, incomplete, ambiguous data or data not related to the diagnosis, treatment or nursing. If the treating physi-

cian fails to agree with such a request by the patient, the consilium of physicians will then decide the validity of the patient's request.

Article 6.735 of the Civil Code grants patients the right to be provided with all their medical documents unless this would be harmful to their health or endanger their lives. If information is withheld, this must be noted in the medical file. The patient is also entitled to ask for copies of the information in his/her medical file at his/her own expense. The healthcare provider must explain the meaning of the information and be willing to make any reasonable corrections or amendments suggested by the patient.

3.18.3.3 The doctor's right to withhold information

According to § 5 of the RPCDH, information can be withheld from the patient:

If the patient so desires, s/he must be supplied with the history of his/her illness or other medical documents of his/hers, with the exception of instances, wherein this may have a basic effect upon the patient's health and even endanger his/her life (this shall be decided by the physician treating him/her, or a physicians' consilium).

In such instances, the treating physician shall note in the disease case history, the limitations of the supply of information.

Article 6.727 of the Civil Code states that providers of healthcare services may withhold information if such information would have a detrimental effect on the patient's health or endanger his/her life. However, the information should then be submitted to the patient's representative and later given to the patient if and when the risk of causing harm no longer exists.

3.18.3.4 The patient's right to refuse information

The right not to be informed is covered by article 6.728 of the Civil Code which states that information should not be provided against the person's will which was clearly expressed and attested by his/her signature. The same right can be found in the RPCDH in article 6 (4). However, in the Civil Code, it is stipulated that the right to refuse information is not applicable if such refusal is likely to be harmful to the patient or to other people.

3.18.3.5 Confidentiality/disclosure of information to other people

Article 10 of the RPCDH deals with the inviolability of personal privacy. The relevant articles are as follows:

1. The private life of patients shall be inviolable. Information concerning the facts of the patients' personal existence may be collected for the case history of the illness, with the patients' consent and if, in the opinion of the treating physician, this shall be deemed necessary for diagnosing the illness, treatment or nursing.

2. All of the information concerning the condition of the patient's health, diagnosis, prognosis and treatment, and also, all of the other information of personal nature concerning the patient, must be held as confidential, even after the patient's death. The laws of the Republic of Lithuania and legal acts of the Ministry of Health shall deter-

mine the procedure of safe keeping of such confidential information. Confidential information may be furnished for other individuals, only upon the written consent of the patient, or if this is stipulated by this and other laws of the Republic of Lithuania.

3. Consent is not required, if the information is provided to individuals who are direct participants in the treatment or nursing of patients, performing expert examinations of the patients' health, and also to institutions, which are given the right by the laws of the Republic of Lithuania to inspect the activity of healthcare institutions.

Article 13 of the same law deals with the use of information in medical files for research and student instruction:

The Lithuanian Committee on Medical Ethics of Lithuania shall establish the procedure for use of the information contained in the patients' documents, for medical research work and student instruction. The personal privacy of the patient must be respected in using information for these purposes.

It is stated in article 6.736 of the Civil Code that healthcare providers may not give information about the patient without his/her consent to other people. Similarly, they may not give copies of official documentation about the patient to other people unless required by law to do so. Information may be provided to people who are involved in the care of the patient if such information is necessary for the provision of such care.

3.18.4 End-of-life care and issues

3.18.4.1 Palliative care

Article 3, § 6 of the Law on the Rights of Patients and Compensation of the Damage to their Health of 1996 states, "Patients shall have the right to be cared for and to die with dignity."

3.18.4.2 Euthanasia and assisted suicide

There is no law against euthanasia but there are legal sanctions against killing. These sanctions are more severe for the killing of a vulnerable person (Council of Europe, 2003).

According to the European Association for Palliative Care (2006), there are no initiatives in Lithuania to seek the legalisation of euthanasia or assisted suicide at the present time.

3.18.5 Bibliography

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3.19 Luxembourg

3.19.1 Consent

3.19.1.1 Consent to medical treatment

Treatment carried out without the consent of the person concerned could technically constitute the offence of assault and battery, although such a case has never arisen. In any case, this would not apply in the case of emergency treatment by doctors or in situations which involve a serious risk to the patient. In such cases the doctor can and indeed must intervene with or without the implicit or explicit consent of the patient.

According to article 8 of the Code of Medical Ethics¹³, doctors are obliged as far as possible to respect the patient's wishes. If a patient is unable to express his or her wishes, his/her relatives must be contacted and informed, except in cases of emergency or if this is impossible. The doctor must make every attempt to explain clearly the effects and consequences of each proposed examination or treatment, except in case of emergency. He/she must obtain the patient's consent, particularly for acts which entail a serious risk (article 9).

It is the doctor's duty when treating a minor or an incapable adult to try to notify the parents or legal representative and to obtain their consent (article 52).

3.19.1.2 Consent in case of emergency

In case of emergency, if the parents or legal representative cannot be contacted, the doctor can give the necessary treatment. However, if the incapable person is able to express an opinion on the matter, the doctor must take it into account as far as possible.

3.19.1.3 Consent in the Law on Hospital Establishments¹⁴

A patient who has been admitted to hospital or a specialised hospital establishment is entitled to receive adequate information on his/her state of health and on any treatment proposed in order to be able to give informed consent. He/she has the right to refuse or accept any diagnostic or therapeutic intervention/treatment. Although, this law provides for the case whereby a complaint can be made on behalf of a patient who is legally or mentally incapacitated, there are no similar provisions regarding consent or refusal of treatment in the case of such a patient.

3.19.1.4 Consent to the donation of organs and/or human tissue

The Law of 25th November 1982 concerning the Removal of Substances of Human Origin addresses the issue of tissue and organ donation from incapacitated people.

According to article 2 of this law, the removal of substances from a living person for the purposes of a graft or transplant to another human being for therapeutic purposes is only possible if the donor is over the legal age of majority, in full possession of his/her

13 The Code of Medical Ethics is more than simply a set of guidelines. It is legally binding due to the fact that it is inscribed in article 4 and article 18 of the Law of 29th April 1983 concerning the exercise of the profession of doctor, dentist and veterinary surgeon. It was also promulgated by the Minister of Health through the Ministerial Decree of 21 May 1991.

14 Law of 28th August 1998 on Hospital Establishments

mental faculties and has given his/her consent freely and in writing. Whereas special provisions exist in the case of minor, there are no special provisions in the case of incapable adults.

In the case of the removal of substances for therapeutic or scientific purposes from a deceased person, this cannot be done if whilst living the person gave written notice of his/her refusal of such removal. In the case of incapacitated adults and minors, removal is possible provided that the legal representative gives his/her authorisation and that the deceased person did not refuse such removal at a time when he/she was capable.

3.19.1.5 Experimental treatment and clinical testing on incapacitated interned adults

According to article 31 of the Law of 26th May 1998 on the placement of people suffering from mental disorders in closed psychiatric establishments or departments, the situation is as follows concerning the administration of certain forms of treatment on people who have been interned due to a mental disorder and who are not in a position to consent:

"No treatment which is not yet generally recognised by medical science, or which presents a serious risk of entailing irreversible damage to the brain or of impairment to the personality, shall be administered unless the doctor considers it to be essential and unless the patient, after being fully informed, expressly consents to such treatment.

Where the patient is incapable of comprehending the significance of the treatment, the doctor shall submit the matter to a committee of three experts, two of whom shall be doctors, appointed by the Minister for Health. The treatment may be administered only if the committee – which shall consider the opinion of the patient's legal representative, if there is one – issues a favourable opinion.

It shall be prohibited to perform on patients any clinical testing of medical products or techniques whose objectives are not those of psychiatric therapy. Where such tests do have objectives of psychiatric therapy, prior authorisation shall be obtained from the Minister for Health, who shall take advice from the Medical Board."

3.19.2 Advance directives/living wills

3.19.2.1 The legal status of advance directives

The Law of 16 March 2009 relating to palliative care, advance directives and accompaniment at the end of life contains a section on advance directives which also includes the possibility of appointing in advance a "trusted person" whom doctors should consult about end-of-life issues when the patient is no longer able to express his or her will.

3.19.2.2 Conditions surrounding the writing, validity and registering of an advance directive

The advance directive and any amendments must be dated and signed by the patient. The advance directive should be available to any doctor responsible for the care of the patient in the terminally ill stage. Alternatively, the patient is free to give the advance

directive to medical staff on the occasion of a hospitalization or at any moment to his/her regular doctor. In all cases, the document should be included in the patient's medical or care file.

3.19.2.3 What an advance directive can cover

A person can express in the advance directive his/her wishes concerning end-of-life treatment and care. This might include the conditions, limits and withdrawal of treatment, including the treatment of pain, as well as psychological and spiritual accompaniment that s/he would like to receive should he/she be in an advanced or end stage of a serious and incurable condition and unable to express his/her wishes.

A trusted person ("personne de confiance") can be designated in the advance directive. The doctor must consult this person if the terminally ill person is no longer able to express him/herself.

An advance directive is not the same thing as an advance written request for euthanasia. Please see the section on euthanasia for details about the latter.

3.19.2.4 Obligation to comply with instructions contained in an advance directive

Article 4 of this law states that doctors must try to establish what the patient's presumed will which involves checking whether he/she wrote an advance directive. The doctor must take into consideration the advance directive in a patient's medical file or which has come to his attention. He/she must evaluate whether the provisions contained in the document correspond to the situation envisaged by the terminally ill patient and take into consideration developments in medical science since it was written. If the doctor decides not to fulfil the patient's previously expressed wishes as contained in the document, he/she must record the reasons for this in the patient's medical file and inform the trusted person, or if there is none, the patient's family.

3.19.2.5 Amending, renewing and cancelling advance directives

The advance directive can be revoked at any time.

3.19.3 Access to information/diagnosis

3.19.3.1 The right to be informed

The contractual nature of the doctor-patient relationship requires the doctor to provide the patient with full information on proposed treatment or examinations. Article 36 of the Code of Medical Ethics permits the doctor to inform the legal representative of an incapable or unconscious person of his/her diagnosis and of relevant medical information.

3.19.3.2 Access to medical files

Article 40 of the Code of Medical Ethics states that the doctor must provide the patient with objective elements of the medical file such as X-rays and the results of tests if s/he feels that this would be useful or if the patient requests such information.

Hospitalised patients are entitled to consult their medical file in accordance with the Law of 28th August 1998 on Hospital Establishments. The patient may exercise this right either personally or through the intermediary of a doctor designated by him/her who does not necessarily have to be attached to the hospital. The patient also has the right to request copies of information contained in the file. In case of death, access to the patient's medical file may be granted to his/her spouse (unless separated), his/her children or any other person who was living with the patient at the time of death.

In accordance with the Law of 31 March 1979 on the Use of Nominative Data in Computer Processing, patients may also have access to computerised information kept on them, although this must be communicated by a doctor designated by the patient for this purpose. Article 22 of this law states that the patient can request the correction, completion, clarification, updating or destruction of personal data if it is inaccurate, incomplete, ambiguous or out-of-date. The patient cannot, however, forbid the recording of such data in this way.

3.19.3.3 The doctor's right to withhold information

Article 51 of this code grants the doctor the right to withhold a serious diagnosis or prognosis from the patient if he/she sincerely believes that there are legitimate reasons for doing so. It is also stated that a fatal prognosis should only be revealed to the patient with the utmost caution. In such cases, the family should generally be informed, unless the patient previously forbade this or designated another person.

3.19.3.4 Confidentiality/disclosure of information to other people

The issue of personal privacy is covered by the Law of 11th August 1982 on the Protection of Private Life. This does not directly address the issue of professional secrecy in the health domain, but this is addressed in article 458 of the Penal Code¹⁵:

"Any doctor, surgeon, health official, pharmacist, midwife, or any other person, who by nature or by profession, is in possession of confidential information entrusted to him/her, and who discloses such information other than in circumstances where he/she is called as a court witness or where the law obliges him/her to disclose such information, shall be punished by imprisonment of between eight days and six months and a fine of between EUR 500 and EUR 5000."

The fact that the revelation takes place in the interests of science does not make it any less of an offence, as the interests of the individual take precedence over those of science. Health professionals are answerable to their patients for any damage caused by a breach of professional confidentiality. A doctor who uses material obtained from his/

¹⁵ The fines and prison sentences are adjusted periodically via a special law. The sentence and fine quoted in this article are thus no longer applicable.

her medical observation of patients for the purpose of scientific communications and publications must ensure that identification of the patient is not possible. Collecting and registering nominal and medical information on computer must be carried out in accordance with the Law of 31 March 1979 on the Use of Nominate Data in Computer Processing.

3.19.3.5 Confidentiality and secrecy in the Code of Medical Ethics

Chapter II of the Code of Medical Ethics deals with professional secrecy. It states that professional secrecy, established in the interests of the patient, is imposed on every doctor subject to the conditions laid down by law. Professional secrecy is total and includes not only what the patient has confided in the doctor, but any information which the doctor might have obtained based on what he/she saw, heard or understood. This obligation extends beyond the patient's death (article 35).

Article 39 states that it is the doctor's duty to make sure that a patient's medical file as well as clinical files and documents containing information on the patient are protected from any form of indiscretion. A medical certificate which contains a medical secret can only be given to the patient in person, who is then free to dispose of it as he/she sees fit. In case of necessity, the doctor can give the certificate to another person, provided that the patient has consented to this. If the patient is incapable or unconscious, the certificate can be given to the patient's legal representative.

3.19.4 End-of-life care and issues

3.19.4.1 Palliative Care

The Law of 16 March 2009 relating to palliative care, advance directives and accompaniment at the end of life addresses several issues linked to palliative care as well some issues which may also be relevant to euthanasia (although there is a separate law on euthanasia and assisted suicide which will be discussed in the next section). The provisions relating to advance directives have already been discussed. The law of 16 March 2009 contains 3 articles which address: 1. the definition of and right to palliative care, 2. the right to abstain from harsh and futile treatment, 3. the double effect.

Article one states that every person in the advanced or terminal stage of a serious and incurable condition, irrespective of its cause, shall have access to palliative care. Such care is available in a hospital establishment or at home. In all cases, cooperation with a hospital is assured and care is provided by a multi-disciplinary trained team. The aim of the care is described as being to cover the physical, mental and spiritual needs of the person and of his/her entourage, and should include the treatment of pain and of psychological suffering.

In article two it is stated that doctors will not be prosecuted for failure to administer treatment to terminally ill patients which they consider inappropriate due to the patient's

condition and which, according to current medical knowledge, would not bring any relief to the patient, improve his/her condition or involve any hope of cure.

Finally, article three stipulates that it is the doctor's duty to relieve suffering and that he/she must provide the necessary treatment to a terminally ill patient even if this would entail a risk of shortening the patient's life. However, the doctor must inform the patient of this risk and obtain his/her consent.

Palliative care is also covered in article 45 of the Code of Medical Ethics which states:

"In the event of incurable or terminal illness, the treating hospital doctor shall palliate the physical and psychological suffering of the patient by giving him/her appropriate treatment, while avoiding "acharnement thérapeutique"¹⁶ and maintaining as far as possible the quality of the life which is coming to an end. The doctor shall assist the dying person until the end, and act in such a manner as to permit the patient to retain his/her dignity. A doctor shall not have the right to provoke deliberately the death of the patient."

The first two sentences of this article are reproduced in article 43 of the Law of 28 August 1998 on Hospital Establishments, which applies solely to doctors treating patients in a hospital establishment.

The Law of 28 August 1998 on Hospital Establishments grants patients suffering from an incurable and terminal illness the right to a dignified death by avoiding "acharnement thérapeutique" and maintaining as far as possible the quality of life. It is stipulated that the doctor must assist the dying person right to the end and act in such a manner as to permit the patient to maintain his/her dignity. It is the doctor's duty to provide palliative care in order to help alleviate physical and psychological suffering. In addition, he/she must also provide the relatives of the patient with adequate assistance to relieve their suffering. Finally, as the patient approaches death, he/she has the right to be permanently accompanied by at least one person of his/her choice in conditions which permit his/her dignity to be respected.

3.19.4.2 Special leave to care for a terminally ill person

Chapter III of the Law of 16 March 2009 relating to palliative care, advance directives and accompaniment at the end of life covers the right to special leave to accompany a person at the end of his/her life. The special leave consists of five days per case per year but can be divided up into smaller units with the agreement of the employer. To benefit from this leave, the employee must provide a medical certificate in which it is stated that the person is in the terminal phase of a serious illness and that his/her permanent presence is needed. During the special leave, the same conditions are applied to the employee as if he or she were personally unable to work due to illness or accident. The period of special leave ends at the latest with the death of the terminally ill person.

¹⁶ This means the relentless pursuit of treatment even when there is no hope of recovery, cure or improvement. This is also covered in the next section on "euthanasia".

3.19.4.3 Euthanasia/assisted suicide

The Law of 19 March 2009 on euthanasia and assisted suicide lays down the conditions which regulate the lawful practice of euthanasia and assisted suicide by doctors and requests by patients for it.

Doctors who respond to a request for euthanasia or assisted suicide will not be prosecuted provided that the following four conditions are fulfilled and the correct procedure followed:

1. the patient must be an adult with capacity who is conscious at the time of making the request.
2. the request is voluntary, considered, repeated and not the result of external pressure.
3. the patient has a terminal medical condition and is experiencing constant and unbearable physical or psychological suffering with no hope of improvement, resulting from an accidental or pathological condition.
4. the patient's request for euthanasia or assisted-suicide has been made in writing.

The doctor must have informed the patient about his/her state of health and life expectancy, and have discussed the issue of euthanasia or assisted suicide with him/her as well as other possibilities such as palliative care and their consequences. He/she must ensure that the request is voluntary, consult another doctor regarding the incurable nature of the condition, consult the "trusted person" if one has been appointed, and check with the National Commission of Control and Evaluation whether the patient has registered a document outlining his/her wishes concerning end-of-life. The patient who made the request for euthanasia or assisted suicide in writing can revoke it at any time.

Any adult with capacity can make an advance written request for euthanasia to be carried out should he/she become terminally ill and unable to express his/her wishes. This statement may contain details of the circumstances and conditions in which this should occur. The doctor may carry out euthanasia on the basis of this document provided that he/she can confirm that:

1. The patient has a serious and incurable condition which is accidental or pathological.
2. The patient is unconscious.
3. This situation is irreversible according to current scientific knowledge.

The advance request for euthanasia must be registered with the National Commission of Control and Evaluation. A doctor who has a terminally ill patient in this above-mentioned situation must consult this National Commission in order to find out whether the patient made such a request.

As for consciously expressed requests for euthanasia, the doctor must consult another doctor as well as the “trusted person” if one has been appointed. Doctors who ensure that the conditions have been fulfilled and follow the correct procedure would not be prosecuted for carrying out euthanasia. No doctor or any other person can be forced to carry out euthanasia or assist in someone’s suicide.

The provisions relating to euthanasia and assisted suicide only apply to doctors and only if certain conditions have been fulfilled and a certain procedure followed. Lay people are not covered by the provisions of this law. For them, laws on assisted suicide and murder would apply.

3.19.4.4 Assisted suicide/non-assistance to a person in danger

A person who helps someone else to commit suicide could be prosecuted for assisted suicide according to article 410-1 of the Penal Code which states that it is a punishable offence not to offer assistance to a person in danger, provided that such assistance would not result in serious danger to oneself.

3.19.4.5 Murder and poisoning

Homicide committed with the intention of bringing about death, i.e. premeditated murder is covered by article 394 of the Penal Code. If death was caused using substances, this would be classed as poisoning according to article 397 of the Penal Code.

3.20 Malta

3.20.1 Consent

3.20.1.1 Consent to medical treatment

In Malta, there is no legislation that deals with the consent to treatment issue comprehensively.

The Constitution has no express reference to the duty of obtaining informed consent, but the notion can be found in the general context of this fundamental law.

Malta is expected to sign and ratify the Council of Europe Convention on Human Rights and Biomedicine in the near future, following which the relevant articles relating to informed consent and research will apply to Malta.

The Data Protection Act that makes provisions for the protection of the individuals against the violation of their privacy by processing of personal data and for matters connected defines "consent" as "any freely given specific and informed indication of the wishes of the data subject by which he signifies his agreement to personal data relating to him being processed."

The "Patients' Charter of Rights and Responsibilities" issued by the Hospital Management Committee refers to informed consent to be given by a patient in hospital.

It states that hospitalized patients have the right to receive clear information concerning their medical condition, to make their own informed decision for treatment, to be well informed and completely free to accept, decline or withdraw any diagnostic or treatment procedure.

The "Patients' Charter" issued by the Malta College of Family Doctors refers to the right of a patient to give or withhold their consent to medical or other care and treatment.

3.20.1.2 Consent to treatment in the case of incapacity

The "Patients' Charter of Rights and Responsibilities" states that under certain circumstances (e.g. children, people with mental disability or dementia) parents or an appointed representative should be fully informed in order to take decisions on behalf of the patient.

If the person is declared by a Court sentence as incapacitated the tutor appointed is the person in charge of giving consent on his/her behalf.

The Mental Health Act (Act XVIII of 1976 and subsequent amendments) rules the compulsory admission for observation or for treatment of a patient in pursuance of an application for that purpose. This application must be made in the interest of the person's own

health or safety or with a view to the protection of other persons. The application shall be founded on the written recommendation of two medical practitioners.

3.20.1.3 Consent in case of emergency

The "Patients' Charter of Rights and Responsibilities" mentioned above, states that "Every hospital patient has the right to make his/her own decisions that have implications on his/her wellbeing, except in those emergencies when the patients lack decision making capacity and a need for treatment is urgent."

In these exceptional cases the treatment can proceed without previous consent.

3.20.1.4 The right to refuse treatment

The "Patient Charter" issued by the Malta College of Family Doctors refers to the right of a patient to "give or withhold your consent to medical or other care and treatment". It also advises patients that they can choose whether or not they wish to take part in research or student training.

3.20.1.5 The right to withdraw consent

The "Patients' Charter of Rights and Responsibilities" issued by the Hospital Management Committee states that hospitalized patients have the right to withdraw consent to any diagnostic or treatment procedure.

3.20.1.6 Consent to the donation of organs and/or human tissue

In Malta there is no presumption of donor. The donor has to express the intention of donating and then a donor card is issued. 15% of the population have a donation card (Eurobarometer, 2007).

3.20.1.7 Consent to research

Malta is expected to sign and ratify the Council of Europe Convention on Human Rights and Biomedicine in the near future, following which the relevant articles relating to research will apply to Malta.

The Bioethics Consultative Committee issued Guidelines Relating to Consent of patients to medical intervention. These Guidelines request specifically that consent of patients to research is necessary and that research should not normally be carried out on those unable to express their consent.

The Data Protection Act (Act XXVI of 2001 and subsequent amendments) provides for the processing of data concerning research and statistics. Article 16 states that (1) Sensitive personal data may be processed for research and statistics purposes, provided that the processing is necessary as stipulated in article 9(e). (2) If the processing referred to in sub article (1) has been approved: (a) in the case of statistics, by the Commissioner himself; (b) in the case of research, by the Commissioner on the advice of a research ethics committee of an institution recognized by the Commissioner for the purposes of this

paragraph; the provisions of sub article (1) shall be deemed to be satisfied. (3) Personal data may be provided to be used for the purposes referred to in sub-article (1), unless otherwise provided by applicable rules on secrecy and confidentiality.

The Data Protection Commissioner has asked the University of Malta to see that all research in Malta is undertaken in accordance with the data protection laws.

The “Patient Charter” issued by the Malta College of Family Doctors advises patients that they can choose whether or not they wish to take part in research or student training.

3.20.1.8 Consent to clinical trials

Following EU Accession, Malta has to adopt EU Directives as part of its own legislation. Three such directives concern the conduct of clinical trials in European countries – 2001/20/EC, 2003/94/EC and 2005/28/EC. These directives, and the respective guidelines explaining their implementation, have considerably changed the way clinical trials are conducted. While the participation of Malta in clinical trials is to be encouraged for various reasons, these have to be regulated according to the legislation set out by the European Union. In themselves, what these Directives strive to achieve are mainly the safety of the study subject and the protection of the investigators from serious consequences.

The legislation concerning clinical trials consists of Directive 2001/20/EC1 (transposed as Clinical Trials Regulations, 20042), Directive 2003/94/EC3 (transposed as Good Manufacturing Practice in Respect of Medicinal and Investigational Medicinal Products for Human Use Regulations, 20044) and Directive 2005/28/EC5 which come into force at the end of January 2006.

Article 6(3) of Directive 2001/20/EC1 and Regulation 7(2) of the Clinical Trials Regulations, 20042 list the points which the Health Ethics Committee should consider when assessing an initial clinical trial submission. The Ethics Committee shall consider among other elements: (g) the adequacy and completeness of the written information to be given and the procedure to be followed for the purpose of obtaining informed consent and the justification for the research on persons incapable of giving informed consent.

3.20.2 Advance directives and healthcare proxies

There is, as yet, no legislation governing advance directives and healthcare proxies in Malta but discussions are underway (Scerri, 2008; Mallia, 2009).

3.20.3 Access to information/diagnosis

3.20.3.1 The right to be informed

The “Patients’ Charter of Rights and Responsibilities” issued by the Hospital Management Committee states that hospitalized patients have the right to receive clear information concerning their medical condition, to make own informed decision for treatment, to

be well informed and completely free to accept, decline or withdraw any diagnostic or treatment procedure.

3.20.3.2 Access medical files

The "Patients' Charter of Rights and Responsibilities" states that the patient has the right to review the records pertaining to his/her medical care and to have the information explained or interpreted as necessary.

3.20.3.3 The right to designate another person to be informed on one's behalf

In Malta, there is no legislation governing advance directives and the same is the case for the designation of another person to act or to be informed on one's behalf in case of future incapacity.

3.20.3.4 The patient's right to refuse information

The "Patients' Charter of Rights and Responsibilities" states that patients have the right not to be informed about their condition or for their condition not to be divulged to next of kin, if this is expressed in writing.

3.20.3.5 Confidentiality/disclosure of information to other people

The Data Protection Act makes provisions for the protection of individuals against the violation of their privacy by processing of personal data and for matters connected. Article 15 on processing concerning health and medical purposes states,

"Sensitive personal data may be processed for health and hospital care purposes, provided that it is necessary for:

- (a) preventive medicine and the protection of public health;*
- (b) medical diagnosis;*
- (c) healthcare or treatment; or*
- (d) management of health and hospital care services."*

Provided that the data is processed by a health professional or other person subject to the obligation of professional secrecy.

The "Professional Secrecy Act" states that all professionals have the duty of respecting confidentiality. The disclosure of information to other people can be a criminal offence.

The patient's privacy is to be respected when discussing his/her medical condition.

The patient has the right to expect that all personal details and records are treated as confidential.

Only in accidental or emergency cases the personal files can be disclosed.

3.20.4 End-of-life care and issues

3.20.4.1 Palliative care

The Malta Hospice Movement is the only provider of palliative care in Malta. The team provides home, hospital, and day care. Officially, there are no palliative care beds in Malta. The Malta Hospice Movement is home-care based. There are no inpatient services.

The Malta Hospice Movement has initiated talks with the state Department of Health to introduce palliative care formally into medical practice in Malta.

It is also in the process of extending its vision and policy to include end-of-life care in accordance with WHO policy and recommendations on the global level. It is hoped that the movement will expand and develop according to the needs of the Maltese people.

The Movement is also in dialogue with the faculty of medicine, as part of endeavors to include palliative care in the undergraduate curriculum.

The Malta Hospice Movement did not officially mark the publication of the Council of Europe report on palliative care (Recommendation Rec (2003) 24 of the Committee of Ministers to member states on the organization of palliative care). However, the movement brought the publication to the attention of the state health authorities and to the faculty of medicine in 2005.

The Malta Hospice Movement has not participated in any way in the Council of Europe discussions about euthanasia (the Marty Report).

3.20.4.2 Special leave for carers in paid employment (to care for a terminally ill person)

According to Triosi and Formosa (2006, p54) there are no formal measures granting special rights such as special leave.

3.20.4.3 Euthanasia

At the current time, there are no initiatives in Malta seeking the legalisation of euthanasia or assisted suicide.

3.20.4.4 Assisted suicide and murder

Assisted suicide and murder are covered in the Criminal Code.

Article 211 of the Criminal Code states:

- (1) Whosoever shall be guilty of wilful homicide shall be punished with imprisonment for life.

- (2) A person shall be guilty of wilful homicide if, maliciously, with intent to kill another person or to put the life of such other person in manifest jeopardy, he or she causes the death of such other person.

Article 213 of the Criminal Code states that:

Whosoever shall prevail on any person to commit suicide or shall give him or her any assistance, shall, if the suicide takes place, be liable, on conviction, to imprisonment for a term not exceeding twelve years.

3.20.4.5 Non-assistance to a person in danger

Article 339, nº 1, j) of the Criminal Code states that a person is guilty of a contravention if “being in duty bound to take care of children, or of other persons incapable of taking care of themselves, neglects to take the necessary care of such children or persons”.

There is discretion of the Court in the application of punishments for contraventions.

3.20.4.6 Murder at the request of the victim

According to Article 213 of the Criminal Code murder at the request of victim is a crime that can be punished with imprisonment for a term not exceeding twelve years.

3.20.5 Bibliography

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3.21 Netherlands

3.21.1 Consent

3.21.1.1 Consent to medical treatment

The WGBO¹⁷, which came into force on 1 April 1995, deals with the issue of consent. Article 450 states that procedures carried out for the purpose of implementing a treatment contract shall require the consent of the patient. If the patient is over sixteen or cannot be considered capable of reasonably assessing his/her own interests with regard to treatment, the care provider and the patient's guardian, mentor, spouse, parent, child or brother/sister may base their decisions on an advance directive (please see the section on advance directives). Kees Blankman (1997) provides the following explanation of how consent is handled in case of an incapacitated adult:

"The introduction of the WGBO illustrates the conviction in the Netherlands that, in general, medical treatment takes place within an agreement, the rights and duties of which are governed by law. If a patient requiring treatment is incapacitated and cannot give his informed consent, an impasse exists, a vacuum that can be filled in several ways. According to Dutch law, the medical professional has no broad statutory authority to act in the best interests of an incapacitated adult. He is entitled and obliged to determine whether or not the adult can decide upon this matter, e.g. entering into an agreement, change of medication, important decisions to be made within the agreement.

If the medical professional considers the patient to be incapacitated, the law requires him to obtain the consent of a representative except in emergency cases and non-radical decisions. Above all, he must act "as a responsible medical professional." This criterion means, among other things, that he must act according to the standards of his profession. These standards will no doubt refer to the best interests of the patient. Following this rule might even result in ignoring the will of the representative.

There are several means of judicial intervention. A representative can start a lawsuit against the professional on the basis of failure to honour the agreement, e.g. not acting as a responsible professional.

Acting as a responsible professional may, on the other hand, imply that the medical professional furthers the application of a measure, e.g. if there is no family member fit to represent the adult or in case there is a dispute within the family. Judicial intervention cannot be requested for a single court order."

Substitute decision making is possible in practically all cases, even in the case of sterilisation. However, it is common for the responsible representative to seek a second opinion. Moreover, if the will of the adult is known, substitute decision making becomes practically impossible.

¹⁷ This is the Dutch abbreviation for the Act of 17 November 1994 amending the Civil Code and other legislation in connection with the incorporation of provisions concerning the contract to provide medical treatment.

3.21.1.2 Consent in case of emergency

If the person who is unable to consent shows the slightest resistance to the treatment or procedure it cannot be continued, except in case of emergency or when necessary to prevent severe harm.

3.21.1.3 The right to refuse treatment

As above.

3.21.1.4 Consent to the donation of organs and/or human tissue

A person must register him/herself as a donor (e.g. via www.wordorgaandonor.nl). If consent has not been given, the doctor may ask for the consent of the family of the deceased person.

3.21.1.5 Consent to research and clinical trials

If a person can no longer consent to participation in clinical research, the family may give consent on his/her behalf.

3.21.1.6 Consent of people who have been involuntarily committed

Under the B.O.P.Z¹⁸, a person who has been involuntarily committed to a psychiatric hospital has the right to be involved in decisions relating to his/her treatment. Article 38 states that a treatment plan must be drawn up in consultation with the patient. If this is not possible, the medical superintendent must be informed. If the person responsible for drawing up the treatment plan is of the opinion that the patient is not in a fit state to assess his/her needs in respect of the proposed treatment, s/he must discuss the issue with the patient's legal representative. If the legal representative is not available the following should be consulted in the order in which they are mentioned:

1. The person named by the patient for this purpose in writing (a self-appointed representative)
2. The patient's spouse or partner
3. A parent, child, brother or sister

If consultation on the treatment plan does not lead to agreement, no treatment may be carried out. Even if agreement has been obtained from the patient or those responsible for consultation, the treatment cannot be administered if the patient later objects. Nevertheless, treatment may be administered if absolutely necessary to prevent danger to the patient or others arising from the disturbance of his/her mental faculties.

In this case, the medical superintendent must be informed immediately upon commencement of the treatment and an investigation must be carried out afterwards to determine whether the decision to proceed with treatment was made with due care and whether the treatment was carried out with due care.

¹⁸ The Act of 29 October 1992 (and subsequent amendments) which replaced the Act of 27 April 1884 on the State Supervision of the Mentally Ill

3.21.2 Advance directives/living wills

Article 450 of the WGBO¹⁹ of 1994 contains a paragraph which can be interpreted as referring to advance directives. It is stated that if a patient aged sixteen or over cannot be deemed capable of reasonably assessing his/her interests with regard to care, the care provider shall comply with the apparent opinion of the patient about withholding consent and refusing treatment expressed in writing while s/he was still capable of reasonable assessment.

3.21.2.1 Conditions surrounding the writing, validity and registering of an advance directive

As stated above, to make a valid advance directive, a person must be aged 16 or over and have the necessary capacity to do so.

3.21.2.2 What an advance directive can cover

It is not stated what an advance directive can and cannot cover, but it is in principle legally binding if it includes withholding consent for future treatment.

3.21.2.3 Obligation to comply with instructions contained in an advance directive

This could include a refusal of treatment or withholding consent in certain circumstances or the request not to be resuscitated. Care providers are legally bound by this written statement but they may deviate from it if there are good reasons for so doing. In a fact sheet produced by the Ministry of Health, Welfare and Sport (1995), it is stated that care providers are not obliged to search for such a statement in emergency situations and that in any case, advance directives must be clear and have been made fairly recently. Moreover, advance directives should not be confused with statements requesting euthanasia.

The Termination of Life on Request and Assisted Suicide (Review Procedures) Act of 2002 contains provisions on advance directives relating to euthanasia. Such a directive may be regarded as a request for euthanasia by the patient if s/he becomes unable to express his/her will. Physicians are not required to perform euthanasia but those physicians who are willing to do so must regard an advance directive as an expression of the will of the patient (Council of Europe, 2003). However, Wortmann (2004) has suggested that an advance directive cannot be used to request active voluntary euthanasia in the case of patients with dementia as the request must have been expressed continuously and steadfastly by the patient over a long period of time.

3.21.2.4 Amending, renewing and cancelling advance directives

Patients may retract or modify an advance directive at any time.

¹⁹ The Act of 17 November 1994 amending the Civil Code and other legislation in connection with the incorporation of provisions concerning the contract to provide medical treatment (came into force on 1 April 1995)

3.21.3 Access to information/diagnosis

3.21.3.1 The right to be informed

The WGBO²⁰ stipulates that the doctor is obliged to provide the patient with information, but also that the patient must furnish the doctor with the information and assistance that s/he may reasonably require in order to implement the treatment contract. The doctor's obligation is linked to the obligation to obtain informed consent. Article 448 states that the care provider must inform the patient clearly and, if necessary, in writing of the proposed examination and treatment, and developments related to the examination, treatment and the state of health of the patient. The Act does not specify how the information should be given, except that it is stated that if the patient is under 12, the information must be provided in a way that s/he understands.

However, in pointing out that "the care provider should be guided by what s/he feels is reasonable for the patient to know in view of the nature and purpose of the examination or treatment, the likely risk, other possibilities and the state of health of the patient", there is an implication that the care provider should bear in mind the patient's needs and wishes and adapt the substance and timing of the information in relation to this. The patient for his/her part is obliged to the best of his/her knowledge to provide the care provider with information and assistance which the latter may reasonably require.

3.21.3.2 Access to medical files

According to the WGBO, the care provider is obliged to keep medical records on the patient. The medical file should contain information relating to the patient's treatment, data concerning the health of the patient, procedures/operations performed and documents containing such information as is necessary for the purpose of providing the patient with the proper standard of care. The file can also contain statements made by the patient in relation to the above. These documents must be kept for 10 years from the date they were produced or for as long as they are necessary for the patient's care.

If the patient would like to consult the medical records, s/he must make a request to do so. The care provider would then be obliged to grant access to the files and provide copies if required, unless this would jeopardise the privacy of a person other than the patient (article 456). The caregiver may charge a reasonable fee for providing copies.

3.21.3.3 The doctor's right to withhold information

The care provider can withhold certain information only if s/he considers that it would cause the patient serious harm. This is known as the "therapeutic exception to the information obligation". In such a case, the care provider can, nevertheless, give the information to another person. If s/he does decide to withhold information, s/he must first consult another care provider on the matter.

3.21.3.4 The patient's right to refuse information

If the patient has expressed a wish not to be informed, information shall not be provided, except where the interest of the patient is outweighed by the harm to him/herself or others which may ensue from withholding it (article 449).

3.21.3.5 Confidentiality/disclosure of information to other people

Concerning access to medical files, the care provider must ensure that no-one other than the patient has access to such documents unless the patient has given his/her consent. Information or access to and copies of documents shall be provided only insofar as it would not infringe on another person's privacy. This is covered by article 457 of the WGBO.

There are, however, several exceptions in that access can be granted to:

- A person with a right to access based on specific legislation
- Those care providers who are directly involved in the patient's treatment
- A person who acts as a locum for the care provider
- Those whose consent was required in connection with the implementation of a treatment plan (the person acting on the patient's behalf, e.g. a guardian)
- Researchers carrying out statistical or scientific research. The care provider must ensure that the data are supplied in such a form as to ensure that they cannot be traced back to the individual. Furthermore, the research must be in the interests of the public, cannot be conducted without the information in question and the patient must not have explicitly objected to information being provided (although s/he may not have actually consented to it).

The care provider must ensure that procedures carried out as part of the treatment contract are not observed by other people, unless their professional assistance is required or the patient has consented to such observation (article 459). This should ensure that the physical privacy of a patient is respected.

3.21.4 End-of-life decision-making/issues

3.21.4.1 Palliative sedation

Palliative sedation is the deliberate lowering of the consciousness of the patient in the terminal stage of life. It means that patients, whose life expectation is no more than two weeks, are brought into a deep sleep and don't receive drinks. This is only for patients for whom there is no longer any possibility of a cure. The goal of palliative sedation is to enlighten unbearable suffering, for example severe pain. Palliative sedation is different from euthanasia because it is not the active termination of life and it is not illegal.

3.21.4.2 Special leave for carers in paid employment (paid leave)

Employees can take paid time off work to sort out emergency situations such as a death in the family or to care for a sick relative. The leave should be reasonable and in keeping with the emergency situation. However, if a person's partner (with whom he or she lives) suddenly becomes ill and needs instant care, the first day off can count as emergency leave but subsequent days cannot. They count as a different kind of leave (Ministry of Social Affairs and Employment, 2007). Ten days' leave can be taken per year to care for a sick child, partner or parent if it is necessary that the employee provides such care. In such cases, the employer must pay at least 70% of the employee's wage. The employer receives compensation for this (Pijl, 2003). Employees do not have legal right to time off work to care for a dying person but employers may agree to grant such leave. It can be granted to people who are close to the dying person even if the latter is in an institution. The leave consists of at least one third of the employee's working hours. The leave can be from one to six months but can be extended to a maximum of 18 months. During this time, the employee receives a payment with a maximum of €490.54 a month paid from public funds (Pijl, 2003).

3.21.4.3 Special leave for carers in paid employment (unpaid leave)

Long-term compassionate leave can be taken by employees who need to take care of a seriously ill child, parent or partner whose life is at serious risk. For a maximum of twelve weeks per year, the employee can take up to half of his/her working hours as compassionate leave. These hours are not paid but the remaining working hours are. They can be spread out over a period of up to 18 weeks subject to agreement with the employer. A request for long-term compassionate leave must be made in writing at least 2 weeks before the requested start of leave. With regard to payment, certain collective labour agreements or other agreements with employers may result in part payment of the hours taken as compassionate leave (Ministry of Social Affairs and Employment, 2007).

The Working Hours (Adjustment) Act 2000 (wet aanpassing arbeidsduur) gives employees the right to increase or decrease their working hours. This right applies to employees in the public and private sector who have been employed by a particular company for at least one year. The request, which can be made once every two years, must be made 4 months in advance and must contain details of the starting date for the change, the magnitude of the adaptation of working time and how the working hours would be divided over the week.

3.21.4.4 Euthanasia

Euthanasia is a criminal offence. However, the articles in the penal code which address taking another person's life or assisted suicide (please see the following sub-sections) were enacted in the late 19th century. Since then a policy decision has been made to distinguish euthanasia from murder and assisted suicide and provide for a lesser penalty than that relating to murder. Article 40 of the Penal Code allows for a "defence of necessity" due to the particular nature of the doctor's task, namely that s/he has the duty to preserve lives but on the other hand has the duty to reduce suffering to a minimum

which leads to a conflict of duties. Consequently, a physician who performs euthanasia or assists with suicide can invoke the defence of necessity. Only doctors can plead this defence as only they have these two duties.

Strictly speaking, neither voluntary euthanasia nor assisted suicide have been legalised or decriminalised in Holland. They remain offences. The defence of necessity is not sufficient in itself. In order to be valid, the doctor must have followed a strict procedure.

Since 1991, there has been an agreement between the Royal Dutch Medical Association and the Dutch Ministry of Justice that gives a doctor protection against prosecution, if in the case of active voluntary euthanasia or assisted suicide, the doctor complies with certain guidelines. The way that the defence of necessity has been interpreted and applied has led to the open practice of euthanasia in Holland. The above-mentioned guidelines are based on criteria established as a result of court decisions which lay down when a doctor can successfully invoke the defence of necessity. The guidelines include the following:

- The patient must make a voluntary request, which should be written down.
- The physician must know the patient well enough to assess whether the request is indeed voluntary and whether it is well considered.
- The request must be persistent and durable.
- The patient's condition must entail unbearable suffering without any hope of recovering. The patient need not be terminally ill to satisfy this requirement.
- The physician must consult a colleague who agrees that the above-mentioned criteria are met.
- The physician must keep a full written record of the case and the decision-making procedure
- The physician performing euthanasia or assisted suicide must not issue a declaration of natural death, but inform the local medical examiner of the circumstances (that it is a physician-assisted suicide).

The notification procedure contains approximately 50 criteria on the basis of which a physician draws up his/her report. The physician reports to the municipal pathologist/coroner, who in turn forwards it with his/her comments to the public prosecutor for assessment.

This assessment takes place on the basis of the statutory norms in the Criminal Code and the way they are interpreted in case law. If the criteria have not been fully met, the doctor will in principle be prosecuted.

Otherwise the public prosecutor will decide not to prosecute the physician as it is likely that the court will recognise the physician's invocation of force majeure.

The decision of the public prosecutor is then put before the committee of procurators-general (chaired by the Minister of Justice), which in individual cases can reverse a public prosecutor's decision not to prosecute (Smook, 1998). Since the case of Chabot (1993/94), if the patient has a psychiatric disorder the doctor must have the patient examined by at least two other doctors, one of whom must be a psychiatrist (Docker, 1996). It is unclear how the process of voluntary euthanasia applies to people with dementia, particularly as it is a lengthy process and the patient may lose the ability to consent as time passes.

3.21.4.5 Withdrawal or withholding of food and drink

The term starvation is used to describe dying as a consequence of food and drink being withheld when a patient is not asking for it spontaneously (or when a patient refuses all food and drink). The patient actually dies as a result of dehydration, which causes the vital organs to stop functioning. The withholding/withdrawal of food and drink under these circumstances is not illegal.

3.21.4.6 Assisted suicide

Assisted suicide is a crime. Article 294 of the Penal Code states that "Any person who intentionally incites another to commit suicide, assists him/her in the act or provides him/her with the means to commit suicide shall, if suicide follows, be liable to a term of imprisonment not exceeding 3 years or a fourth category fine".

3.21.4.7 Murder at the request of the victim

According to article 293 of the Penal Code, "Any person who takes another person's life at that person's express and earnest request shall be liable to a term of imprisonment not exceeding 12 years or a fifth category fine".

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3.22 Norway

3.22.1 Consent

3.22.1.1 Consent to medical treatment

Chapter 4 of the Patients' Rights Act of 1999 addresses the issue of consent to healthcare. Section 4-3 contains a few relevant provisions:

- To have the right to consent to healthcare, a person must be at least 18 years of age and have legal capacity.
- Competence to give consent may cease to apply wholly or partly if the patient, on account of a physical or mental disorder, dementia or mental retardation, is clearly incapable of understanding what the consent entails. The healthcare provider shall decide whether the patient lacks competence to give consent. Based on the patient's age, mental state, maturity and experience, health personnel shall do their best to enable the patient himself or herself to consent to healthcare.
- A decision concerning lack of competence to give consent shall state the reasons for the decision and shall be given in writing, and if possible shall immediately be presented to the patient and his or her next of kin. If the patient has no next of kin, the decision shall be presented to health personnel.

If a person has legal capacity but is nevertheless not competent to give consent, the healthcare provider can decide on his/her behalf for healthcare that is not of a highly invasive nature. In other cases, the person's next of kin may consent on his/her behalf (section 4-6). If he or she does not have any next of kin, a healthcare provider may consent on his/her behalf after consultation with other qualified healthcare professionals (section 4-8).

People who have been declared legally incapacitated pursuant to the Act relating to the declaring of a person as incapable of managing his own affairs of 28 November 1898 may consent to healthcare themselves to the greatest possible extent. If they are unable to do so, their guardian may give consent on their behalf (section 4-7).

3.22.1.2 Consent in case of emergency

Paragraph 7 of The Health Personnel Act of 1999 deals with the question of emergency healthcare. It states: Health personnel shall immediately provide the healthcare they are capable of when it must be assumed that the healthcare is of vital importance.

Pursuant to the limitations laid down by the Patients' Rights Act (§ 4-9), necessary healthcare shall be given, even if the patient is incapable of granting his or her consent thereto, and even if the patient objects to the treatment.

3.22.1.3 The right to refuse treatment

In January 2009, the Act amending the Patients' Rights Act was implemented. It resulted in the implementation of a new section in the Patients' Rights Act entitled "healthcare for patients without competence to give consent to healthcare etc." The purpose of this new section is described in the Act as being to provide necessary healthcare in order to prevent significant harm to health and to prevent and limit the use of force.

The new section deals with the provision of healthcare to patients who lack the capacity to consent and are refusing to accept healthcare. It also covers involuntary admission to or detention in a health institution and the use of restraining measures if considered necessary.

Under § 4a of the Patients' Rights Act, a person can be given compulsory healthcare if the following conditions are met:

- the patient is 16 years or older
- the patient is considered as a person without consent
- the patient is refusing to accept healthcare

On the basis of the Act and an examination conducted by an authorised doctor, or another authorised person responsible for care, the application is issued and forwarded to the Norwegian Board of Health Supervision, of which there is an office in each county.

Moreover, it is clearly stipulated that when appraising the need for care it should be considered whether the patient constitutes a danger to him/herself should the compulsory measures not be provided. Compulsory measures must be deemed necessary and be proportionate to the need for healthcare. Moreover, acceptable voluntary solutions must have been tried prior to any compulsory measures being implemented.

Decisions for compulsory healthcare can be made for a period of up to one year at a time. A description of the care and treatment needed must be appended to the application. If the decision concerning the compulsory measures is for more than three months the decision is automatically sent to the Norwegian Board of Health Supervision for evaluation.

The patient or the family carer has the right to appeal. The deadline for the appeal is three weeks after the decision has been made. The appeal is directed to the Health Supervision, although it is sent to the local health authorities for an immediate second evaluation of the decision.

3.22.1.4 The refusal of life-saving treatment

A dying patient is entitled to refuse life-prolonging treatment. If a dying patient is incapable of communicating his/her wishes regarding treatment, the healthcare personnel may withdraw healthcare provided that the patient's next of kin also consent and that

the healthcare personnel, based on an independent evaluation, find that this also corresponds with the patient's wishes. Healthcare personnel must ensure that the patient was given adequate information and understood the consequences of the refusal of treatment for his/her own health. The patient must also have legal capacity (§ 4-9).

3.22.1.5 The right to withdraw consent

Consent can be withdrawn at any time (European Commission, 2006).

3.22.1.6 Consent to the donation of organs and/or human tissue

The Biobank Act of 2003 covers the issue of consent to the donation of human biological materials to biobanks, either for diagnostic and treatment purposes or for research purposes.

For donations intended for diagnostic and treatment purposes from people who do not have the capacity to consent (according to section 4-3 of the Patients' Rights Act), sections 4-6 to 4-8 of the same act apply. In the case of donations intended for research purposes, articles 4-7 and 4-8 of the Patients' Rights Act apply. The amended paragraphs regarding the Biobank Act are still not implemented.

3.22.1.7 Consent to research and clinical trials

In the Act of Health Research, which has not been yet implemented, consent to research and clinical trials is specifically mentioned. Prior to this Act no legislation dealt specifically with consent either to research or to clinical trials.

The Act of Health Research specifies that consent must be voluntary, informed and documented. The regulations of consent are to be issued by the Department of Health. However if the people in the research and trials are incapable of consent, the approval and responsibility for consent is governed by the provisions of the Act of Patients' Right part 4-3.

3.22.2 Access to information/diagnosis

3.22.2.1 The right to be informed

Section 3-2 of the Act relating to Patients' Rights of 1999 states that patients are entitled to have all the information they need to gain an insight into their health condition and any healthcare provided. This information may be given to the patient's next of kin if s/he consents or if the circumstances justify this. If the person is over 16 years of age, obviously incapable of safeguarding his or her own interests due to dementia (for example), both the patient and his/her next of kin are entitled to receive this information (section 3-3).

When information is given, healthcare professionals should ensure that the patient has understood its content and significance. It should be given in a considerate way, bearing

in mind the patient's age, maturity, experience and cultural and linguistic background. It should be noted in the patient's medical file that s/he has been informed (section 3-5).

3.22.2.2 Access medical files

Section 5-1 of the Act on the Rights of Patients covers the right of access to medical files. Patients are entitled to access their medical records including enclosures and upon special request to have a copy. They are also entitled to a brief and simple explanation of any medical terms used. Patients may demand that information in their medical file be corrected or erased pursuant to the provisions of sections 42 to 44 of the Health Personnel Act.

Next of kin who are entitled to health-related information are automatically entitled to access the patient's medical file. However, access to medical records may be refused for the same reasons as access to general information can be refused.

A representative of the patient may access information that has been refused to the patient unless the representative is considered unfit for this task.

The patient's next of kin are entitled to have access to his/her medical records after his/her death, unless there are specific reasons to refuse such access.

3.22.2.3 The doctor's right to withhold information

Information may be withheld if absolutely necessary to prevent endangering the patient's life or seriously damaging his/her health. It may also be withheld if it is clearly inadvisable to provide such information out of consideration for people who are close to the patient (section 3-2).

3.22.2.4 The patient's right to refuse information

A patient's request not to receive information about his/her health should be respected unless it is necessary in order to prevent harmful effects caused by the healthcare. This is not mentioned in the legislation but in the guidelines for healthcare. It does not cover side-effects to treatment.

3.22.2.5 Confidentiality/disclosure of information to other people

According to section 3-6 of the Act on the Rights of Patients of 1999:

Medical and health-related information and other personal information shall be treated in accordance with the current provisions regarding confidentiality. The information shall be treated with caution and respect for the integrity of the person whom the information concerns. The duty of confidentiality ceases to apply to the extent that the person entitled to confidentiality so consents.

Provisions relating to the confidentiality of information can also be found in the Act relating to Health Personnel, the Act on Specialised Health Services and the Act on Personal

Health Data Filing Systems and the Processing of Personal Health Data (European Commission, 2006).

Cooperation with carers and their right to information are covered in different laws and regulations.

Cooperation with carers is specifically mentioned in both the regulations on nursing homes (§ 4-11, 4-12), which include an obligation to ensure that people living in such homes have a better stay, and in the Act on the Rights of Patients of 1999. The Act on the Rights of Patients covers the carer's right to information and mentions the importance of effective communication strategies, especially in the newly amended paragraph on information and cooperation with carers, so as to provide the best possible medical assistance to patients.

The Act on Special Healthcare also specifies the hospital's duty to give information and education to carers (§ 3-8). For other services for carers the municipal's social service, according to the Act of Social services, shall comprise measures to provide respite for persons and families with especially burdensome caring work, and pay to persons with especially burdensome caring work.

3.22.3 Advance directives and healthcare proxies

Advance directives are not legally binding in Norway but people do nevertheless write them. In fact, there is an organisation called "Right to a worthy death" which offers help, advice and assistance in filling in advance directive forms. Independent witnesses are required. An advance directive may be withdrawn or amended at any time by a person with capacity. However a guideline for decisions regarding prolonging treatment for seriously ill and dying persons is being made and will be issued in 2009.

Meanwhile, § 4-9 of the Act on the Rights of Patients states that a dying patient is entitled to object to life-supporting treatment. Healthcare professionals must however ensure that the patient mentioned is of legal age, and that the patients are given adequate information and have understood the consequences of the refusal of treatment. If the patient is incapable of communicating his/her wishes, the healthcare personnel may withdraw healthcare provided that the patient's next of kin so requests and that the healthcare personnel, on the basis of an independent evaluation, finds that this also corresponds to the patient's wishes. Presumably such wishes may be recorded in an advance directive.

3.22.4 End-of-life care issues

3.22.4.1 Palliative care

There is no legislation specifically covering palliative care, but different regulations and guidelines do make general reference to this as a topic of care. The Regulation of Qualita-

tive Care in the Municipality covers the topic in the regulation that the best possible care is to be given at all times, whether at home for the patient or in a nursing home.

3.22.4.2 Special leave for carers in paid employment (to care for a terminally ill person)

According to current legislation special leave exists for carers in paid employment. It is specified in the Act of Working Environment that carers in paid employment are entitled to special leave to care for a terminally ill person for 20 days (The Act of Working Environment § 12 -10). This is not, however, a statutory right. In this period of leave the carer has the right to a nursing allowance according to chapter 9 of the Norwegian Social Insurance Scheme.

The Ministry wants the right for special leave to care for terminally ill person to be a statutory right and a hearing is now underway. The hearing also covers the possibility of extending the period of special leave from 20 to 60 days. In addition, the ministry of health is suggesting that the nursing allowance be increased from 20 days to 60 days. The Ministry of Labour further suggests that entitlement to the allowance should be for three months after a period of prolonged nursing ends due to the death of the care recipient.

Retirement and disability pensioners who are supporting a spouse and/or children under the age of 18 may obtain a means-tested dependant supplement.

The dependant supplement is a supplement to the pension which depends on the person's income. It is awarded to persons in receipt of pension who support a spouse and/or children and who have a combined income below a certain level.

3.22.4.3 Special leave for carers in paid employment (to help family members over the age of 18 years with special needs)

Carers have no statutory right to special leave to help their adult relatives in case of need. A hearing took place early in 2009 concerning a proposition on leave of absence for family carers for a period of ten days during a calendar year, to assist their relatives over 18 years of age with simple actions e.g. going to the doctor's, dentist's etc. These acts are too simple to be considered part of homecare services, but sometimes too difficult for people to manage on their own.

According to the Ministry of Labour, the reason for giving family carers statutory right of leave to help relatives is to increase awareness of the important role that carers play in providing informal care nowadays. If the proposal is adopted, the amendments will fall under the regulations of the Working Environment Act (§ 12-10).

3.22.4.4 Euthanasia

According to section 233 of the General Civil Penal Code, "any person who causes another person's death, or who aids and abets thereto, is guilty of homicide and shall be liable

to imprisonment for a term of not less than six years." If the act was committed with pre-meditation, the term of imprisonment can be for up to 21 years.

3.22.4.5 Assisted suicide

Section 236 in the General Civil Penal Code deals with assisted suicide. It states that any person who aids or abets another person to commit suicide shall be liable to the same penalty as for aiding and abetting a homicide. No penalty is imposed if the act does not lead to death or considerable injury to the body or health of the other person.

The punishment may be less severe if the person who killed or assisted in the killing of a terminally ill person was moved by compassion to do so (§ 235).

3.22.4.6 Non-assistance to a person in danger

The Norwegian criminal code specifies that when someone does not try to prevent an action which is illegal he or she can be faced with an accusation in virtue of the code relating to murder or manslaughter. If the action was done in ignorance the accusation is made taking into consideration how the situation was in fact understood by the accused.

3.22.4.7 Murder at the request of the victim

The Norwegian criminal code does not specifically deal with assisted suicide or murder at the request of the victim. However a person who does not try to prevent an action which is illegal can be faced with an accusation in virtue of the code relating to murder or manslaughter. This implies that not trying to stop someone from committing suicide is considered as aiding or abetting a suicide.

3.23 Poland

3.23.1 Consent

3.23.1.1 Consent to medical treatment

Under the Physician's Profession Act of 5 December 1996, in order to carry out examinations or provide other medical services, doctors must have first obtained the consent of the patient. If the patient does not have sufficient capacity to consent, it may be given by his/her legal representative. If s/he does not have one or the legal representative cannot be contacted, then the Guardianship Court must provide consent.

The issue of consent to medical operations is also addressed in the Penal Code. Article 192 states that whoever performs a medical operation without the consent of the patient shall be subjected to a fine or up to 2 years' imprisonment.

According to Art. 34.1 of The Physician's Profession Act 1996, the patient has the right to express his/her written consent to surgical operation or application of treatment methods.

3.23.1.2 Consent in case of emergency

It is possible for a doctor to examine or treat a person without prior consent if immediate medical attention is needed and there is no time to obtain consent, or alternatively, if the patient is incapable of expressing his/her will "due to advanced age" and his/her legal or de facto representative cannot be contacted (art. 33, § 1) (Kiejna et al., 2008).

3.23.1.3 The right to refuse consent

The patient has the right to express his/her consent to accept defined health services or to refuse them after having been granted appropriate information. The consent of the patient, and in the case of minor patients or persons incapable of expressing their wishes, the consent of the legal representative or the guardian-in-fact or guardianship court, is the basis for a physician to act. (The Ministry of Health Charter of Patient Rights, December 1998)

NB. Patients' rights are regulated in many different legal acts. The most important one is the Act of 30 August 1991 on Healthcare Institutions. The general right to healthcare of every citizen is granted in article 68.1 of the Polish Constitution.

3.23.1.4 The right to withdraw consent

There is no provision with regard to the withdrawal of consent in the case of a normal medical treatment. The patient has the right to express consent to a medical experiment, after having obtained information on the aims, conditions, methods, benefits and risks, and also has the right to withdraw consent to such an experiment (Art. 24 and 25.1 of the Healthcare Institutions Act, 1991).

3.23.1.5 Consent to non-conventional treatment

The patient has the right to express, orally or in writing, his/her consent to ANY treatment (Art. 32.1 and 7 in The Physician's Profession Act of 5 December, 1996 and Art. 19.1 in the Healthcare Institutions Act of 30 August 1991).

The patient has the right to express consent to a medical experiment, after having obtained information on the aims, conditions, methods, benefits and risks, and also has the right to withdraw consent to such an experiment (Art. 24 and 25.1 of the Healthcare Institutions Act, 1991).

3.23.1.6 Consent to the donation of organs and/or human tissue

Under the Donation, Storing and Transplantation of Human Cells, Tissue and Organs Act of 1 July 2005, the patient has the right to:

- express consent to donate his/her organs or tissue (Art. 9.1, p.7);
- express his/her refusal to donate organs and tissue after his/her death as well as to withdraw such refusal at any time (Art. 4 and 5);
- personal data protection in connection with donation or transplantation of his/her organs (Art. 12.1).

3.23.1.7 Consent to research

According to Kiejna et al. (2008), the legal representative of a person entirely lacking capacity can consent to "healing research" on his/her behalf. If the person lacking capacity is nevertheless capable of voicing an opinion on the matter, his/her written consent should also be obtained. If the legal representative refuses to consent to such research, consent can be sought from the guardianship court.

For people with full legal capacity who are not able to give their opinion about proposed healing research, the guardianship court can consent on their behalf.

If it is not possible to delay the healing research on account of imminent danger to life, consent is not necessary.

3.23.1.8 Consent to clinical trials

Under Art. 37 b.2 p.2 and Art. 37 f of the Pharmaceutical Act of 6 September 2001, the patient has the right to express his/her consent to clinical trials and the right to withdraw such consent. The physician is obliged to give the patient detailed information on the procedure, methods and risks involved in participating in a clinical trial.

3.23.2 Advance directives and healthcare proxies

There is no legal framework in Poland for the use of advance directives in healthcare and for end-of-life decision making (Kiejna et al., 2008).

3.23.3 Access to information/diagnosis

3.23.3.1 The right to be informed

Under Art. 31.1-3 of the Physician's Profession Act of 5 December 1996, as well as Art.19.1 p.2 of The Healthcare Institutions Act of 1991, the patient, or his legal representative, has the right to be informed about his/her health condition, diagnosis, suggested treatment methods, treatment results. The physician is obliged to provide to the patient or his/her legal representative clear information on the health condition, diagnosis, suggested and possible diagnostic and treatment methods, foreseeable consequences of their application or omission, and the results of treatment. The scope and object of information is very broad. The physician can only hide such information, when the patient expresses such a wish or demand.

3.23.3.2 The right to access medical files

Under Art.18 § 52 of The Healthcare Institutions Act, the patient has the right to access both individual and collective health files. Access to the individual medical documentation in the healthcare institutions should be provided through an oral or written request of the patient or his/her legal representative. The patient has the right to access the collective medical documentation upon written request. Access is limited to the data of the patient. The patient has the right to request copies and certified copies of his/her medical documents.

3.23.3.3 The right to designate another person to be informed on one's behalf

Under The Healthcare Institutions Act 1991, Art. 20.2, 26 and The Physician's Profession Act 1996, Art. 31.2, the patient has the right to appoint another person to be informed about his/her health by the doctor.

3.23.3.4 The doctor's right to withhold information

The physician may withhold information only on the request or demand of the patient (Art. 31 of The Physician's Profession Act of 5 December 1992). However, according to Art. 31.4 of The Physician's Profession Act, in special circumstances, when prognosis is unsatisfactory, a physician may limit the amount and scope of information on the patient's condition, if the physician regards it as in the patient's good interest. In such cases the physician informs the patient's legal representative or a person who has been authorised by the patient to obtain information on his/her behalf.

3.23.3.5 The patient's right to refuse information

Under the 1996 Physician's Profession Act, Art.31.3, the patient has the right to ask the doctor not to disclose information on his/her condition.

3.23.3.6 Confidentiality/disclosure of information to other people

Medical secrecy is recognized in penal and civil procedures. According to Article 261.2 of The Code on Civil Procedure, as a witness at the Civil Court, the physician has to invoke the medical secret and refuse to give protected information. The obligation to keep

information confidential can be lifted by The Court. According to Article 180.2 of The Code of Penal Procedure, during the examination of the physician, medical secret can be lifted only when it is justified by the common interest, and there is no other possibility to obtain information in any way.

A physician has the duty to maintain confidential any information related to the patient and obtained while performing his/her duty. Without the patient's consent, a physician cannot reveal any information to the patient's family members, unless the interest of the patient requires it, but not when the information may be used against the patient (e.g. in a divorce case).

On 29 August 1997, the Protection of Personal Data Act was adopted. It stipulates that everybody has the right to the protection of his/her personal data, including medical data.

3.23.4 End-of-life care and issues

3.23.4.1 Palliative care

Under the Constitution of 2 April 1997, every citizen has the right to health protection and the authorities should provide equal access to health services financed from public funds. Among such health services, listed in The Health Institutions Act, as well as in Article 15 of The Health Services Act of 27 August 2004, there is palliative and hospice care, available both for adults and children. For the past two years the Ministry of Health has been working on a new regulation on standards and medical procedures applied in palliative care in health institutions.

There are over 500 facilities in Poland specially designed to offer palliative care, run by the state or non-profit organizations. They mostly admit cancer patients. It is rather uncommon for persons with dementia to be admitted to such institutions.

3.23.4.2 Special leave for carers in paid employment (to care for a terminally ill person)

People who care at home for an adult member of their family, regardless of the diagnosis, are entitled to 14 days' sick leave in one year as well to a care benefit under The Family and Care Code of 25 February 1964, revised on 7 October 2007, and The Social Benefits Act of 25 June 1999, articles 32.1 and 33.1 and 2. Those carers/parents who look after sick children of up to 8 years old are entitled to 60 days' leave each year. They need a certificate from a doctor, who is responsible for the patient's treatment, to prove they are entitled to such leave. There is no regulation regarding terminally ill patients and their carers who might be entitled to special benefits or leave.

3.23.4.3 Euthanasia/assisted suicide

The following extracts from the Penal Code may be of relevance to the issue of euthanasia and assisted suicide (including murder at the request of the victim and non-assistance to a person in grave danger).

Article 150.

§ 1. *Whoever kills a human being on his/her demand and under the influence of compassion for him/her shall be subject to the penalty of the deprivation of liberty for a term of between 3 months and 5 years.*

§ 2. *In some extraordinary circumstances the court may apply an extraordinary mitigation of the penalty or even renounce its imposition.*

Article 151.

Whoever by persuasion or by rendering assistance induces a human being to make an attempt on his/her own life shall be subject to the penalty of the deprivation of liberty for a term of between 3 months and 5 years.

3.23.4.4 Non-assistance to a person in danger**Article 162.**

§ 1. *Whoever does not render assistance to a person who is in a situation threatening an immediate danger of loss of life, serious bodily injury, or a serious impairment thereof, when s/he could do so without exposing him/herself or another person to the danger of loss of life or serious harm to health shall be subject to the penalty of deprivation of liberty for up to 3 years.*

3.23.4.5 Murder at the request of the victim

According to the Penal Code (Article 151) this is regarded as a serious crime. However, in extraordinary situations, the judge can even renounce the imposition of a penalty.

3.23.5 Bibliography

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3.24 Portugal

3.24.1 Consent

3.24.1.1 Consent to medical treatment

According to Article 156^a of the Penal Code, a health intervention carried out without consent is a crime that can be punished by 3 years' imprisonment.

Clause 5 of the Mental Health Act No. 36/98 of 1998 on the rights and duties of the user covers the issue of consent. The following provisions are included:

- Users of mental health services are allowed to decide to receive or refuse any diagnostic and therapeutic intervention which they are proposed, except in the case of compulsory internment or in emergency cases where non-intervention would create proven risks to the person concerned or any other person;
- For electroconvulsive therapy prior written consent must be obtained;
- Within the terms of the legislation in force, patients may accept or refuse to take part in investigations, clinical tests or training activities.

The above rights extend to the person's legal representative in cases of incapacity.

For psychosurgical interventions, prior written consent must be obtained and two written statements from psychiatric doctors designated by the Conselho Nacional de Saúde Mental must be obtained.

3.24.1.2 Consent in case of emergency

In emergency cases the health professional can act without consent. This is covered by article 156 § 2 a) of the Criminal Code.

3.24.1.3 The right to refuse treatment

According to article 14, 1 b) of the Basic Health Law 48/90 of 24 August, a person has the right to refuse treatment. If the person is declared incapable the guardian or the tutor has the right to refuse on the person's behalf.

3.24.1.4 The right to withdraw consent

The withdrawal of consent is possible at any time. This is covered by article 38 § 2 of the Criminal Code.

3.24.1.5 Consent to non-conventional treatment

The principles and rules are the same as for conventional treatment. Consent has to be obtained.

3.24.1.6 Consent to the donation of organs and/or human tissue

The donation of organs is foreseen in Law 12/93 of 22.04 amended by the Law 22/07 of 29.06 (please see attached).

Insofar as donations are concerned, consent is always necessary when the potential donor is alive. In the case of people with incapacity only the legal representative or the court may give consent. Donation is never possible (for people with incapacity) for organs that cannot be regenerated.

Insofar as post-mortem donations are concerned, in Portugal everyone is presumed to be a donator. However, there is a National Register of non donators. If someone does not want to donate his/her organs, or some of them, this has to be registered there.

3.24.1.7 Consent to research

The Law on Mental Health No. 36/98 of 24 July 1998 contains a clause which covers the rights and duties of the people who have recourse to mental healthcare (not only those who have been interned). According to clause 5, people have the right to accept or refuse to take part in investigations, clinical tests or training activities. However, if it is judged that a person is incapable of evaluating the meaning or extent of consent to the above, the decision can be taken by his/her legal representative.

3.24.1.8 Consent to clinical trials

Law No. 46/2004, of 19 August 2004 adopted Directive 2001/20/CE and repealed the Decree-Law No. 97/94 dealing with participation in clinical trials. Under article 6 (1) (d), informed consent is required and should be written, dated and signed. It should be given freely by the participant after having been duly informed of the nature, significance, implications and risks of the trial. If the participant is not capable of giving his/her consent a legal representative should give it (article 7 - minor/article 8 - mental health).

In Portugal, the relevant clauses of the European Convention on Human Rights and Bio-medicine Rights are also applicable.

3.24.2 Advance directives

Advance directives are not recognised in Portugal.

3.24.3 Access to information/diagnosis

3.24.3.1 The right to be informed

According to article 157 of the Penal Code consent is only valid if the person is duly informed about the diagnosis, and the characteristics and risks of the intervention.

The new Code of Medical Ethics (Regulamento nº 14/2009 of 13/01/2009), which replaced the 1985 Code of Medical Ethics, addresses the issue of informing the patient of his/her

state of health. According to article 50, the diagnosis and prognosis should be revealed to the patient so as to respect his/her dignity and autonomy.

The right to information is also covered by the Law on Mental Health which grants the patient the right to be informed, in an adequate fashion, of his/her rights, as well as the plan for therapy being proposed and the predicted effects (clause 5). The relevant articles of the European Convention on Human Rights and Biomedicine Rights are also applicable.

3.24.3.2 Access medical files

It is stated in article 35 of the Portuguese Constitution that all citizens have the right to access any computerized data relating to them and to be informed of how the data is to be used. Not all medical files are computerised. However, a person has the right to access any data concerning him/herself, irrespective of whether it is computerised or not.

Law No. 12/2005 of 26 January 2005 concerning personal genetic information and health information grants a person the right to consult his/her complete medical records (unless there are exception circumstances whereby doing so would be clearly harmful to him/her). Article 2 of this law also grants a person the right to have his/her medical records made available to other specified people (Nys et al., 2008).

3.24.3.3 The doctor's right to withhold information

Article 50º of the new Code of Medical Ethics does not exactly state that the doctor may withhold the diagnosis and prognoses under certain conditions. However, it states that the doctor has to be very careful when communicating them and to balance the damage the information may cause the person. This is also covered by article 157 (§ 3B) of the Criminal Code.

3.24.3.4 The patient's right to refuse information

The right not to know is not covered in Portuguese health law or Law No. 12/2005 of 26 January 2005 concerning personal genetic information and health information (Nys et al., 2008). However, article 50º, nº 3 of the new Code of Medical Ethics covers the right to refuse information.

Moreover, according to the principle of the fundamental right of self determination, a person has the right to refuse information and this right must be respected by his/her doctor.

3.24.3.5 Confidentiality/disclosure of information to other people

Article 50 of the new Code of Medical Ethics of 2009 states that diagnoses and prognoses should only be revealed to third parties (e.g. relatives) with the patient's permission unless the latter is cognitively impaired.

According to article 195 of the Portuguese Criminal Code, a person may be imprisoned for up to one year or fined if, without prior consent, s/he discloses secret information obtained through his/her civil state, office, job or activities.

Personnel responsible for the processing of genetic and health-related information are obliged under Law No. 12/2005 of 26 January 2005 to take the necessary steps to protect the confidentiality of such information.

3.24.4 End-of-life care and issues

3.24.4.1 Palliative care

There is a National Programme on Palliative Care which was approved by a ministerial decision (by the Minister of Health) on 15/06/2004.

According to this document, palliative care is based on the fundamental conception that no one can make decisions about the life of a human being, which means that nothing shall be done to anticipate or delay death and that consequently euthanasia, assisted suicide and diagnostic or therapeutic futility are rejected (1. Principle g).

In 2006, the National Network of Integrated Continuous Care (Rede nacional de cuidados continuados integrados – RNCCI) was approved. Its aim is to provide continuous care through complementary levels of integrated care (convalescence, rehabilitative middle and long-term care) as well as palliative care for the elderly and for those living in a situation of dependency. (<http://www.rncci.min-saude.pt/index.aspx?p=MenuPage&Menuld=7>).

3.24.4.2 Special leave for carers in paid employment (to care for terminally ill person)

There is no specific special leave to care for terminally ill person.

However, article 252º of the Labour Code states that employees are entitled to 15 days per year leave to take care of their spouse or a person living in civil union (de facto union) or in the same home sharing expenses (common economy) or a direct or in-law member of the family. There must be a need for urgent and unavoidable care.

In case of a handicapped person or someone with a chronic disease the leave can be for up to 30 days per year.

3.24.4.3 Euthanasia/assisted suicide

Passive euthanasia, which involves the withholding of life-preserving measures, is illegal and could be considered an “omission of assistance” (please see relevant section below) by the physician or homicide, depending of the facts.

Under article 131 of the Penal Code, direct active euthanasia is a homicide, even if it is carried out in order to hasten a painful death.

Article 135 of the Penal Code: Incitement and assistance to commit suicide:

1. *Whoever incites another to commit suicide or assists a person in doing so, will receive a prison sentence of up to 3 years, if the suicide was attempted or accomplished.*
2. *If the person incited or assisted is less than 16 years old or, for any reason, has his/her capacity or determination markedly diminished, will receive a prison sentence of between 1 and 5 years.*

3.24.4.4 Non-assistance to a person in danger

Article 200 of the Penal Code: Omission of Assistance:

1. *Whoever, in case of a serious need, namely caused by disaster, accident, public disaster or a state of common danger, which endangers life, physical integrity or freedom of another person, fails to provide assistance necessary to the removal of hazard, either by personal action or by promoting rescue, will receive a prison sentence up to one year or a penalty of fine of up to 120 days.*

3.24.4.5 Murder at the request of the victim

Article 134 of the Penal Code: Murder at the request of the victim:

1. *Whoever kills another person determined by a real, instant and expressed request that he/she has made, will receive a prison sentence of up to 3 years.*

3.24.4.6 Murder

The crime of simple murder is the fundamental legal type of murder in Portugal. However, other kinds of murder exist, such as qualified murder, privileged murder, murder at the request of the victim, incitement and assistance to commit suicide, infanticide and negligent homicide (some of which have been mentioned above).

Article 131 of the Penal Code: Murder:

Whoever kills another person will receive a prison sentence of between 8 and 16 years.

3.24.5 Bibliography

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Nys H. et al. (2008), *Patients Rights in the EU – Portugal*, European Ethical-Legal Papers No. 13, Leuven

Information from the “Conselho nacional de ética para as ciências da vida” on interdiction and incapacity

3.25 Slovakia

3.25.1 Consent

Act No. 576/2004 Coll. of 21 October 2004 on healthcare, health-related services and on the amendment and supplementing of certain laws (hereafter referred to as the Act on Healthcare) seems to be the main law governing patients' rights and decision making in the context of healthcare. Unless otherwise stated, the references in this report on healthcare and decision making in the Slovak Republic will be to the relevant sections and paragraphs in the Act on Healthcare.

3.25.1.1 Consent to medical treatment

Informed consent must be given prior to the provision of healthcare (§ 4.4). It should be given by person to whom the healthcare is to be provided or by a legal representative if that person lacks the capacity to give informed consent. Patients with incapacity should participate in the decision-making process to the greatest extent possible (as determined by their level of capacity) (§ 6.5)

Details of the informed consent including a statement made by patients with incapacity should be recorded in the medical file.

3.25.1.2 Consent in the case of emergency

Emergency care can be provided without informed consent if it is impossible to obtain in time and if such consent could be presumed. Inpatient care can be provided without informed consent if the person is a danger to him/herself or to his/her environment due to a mental illness or if he/she has symptoms of a mental defect or if there is a risk of serious deterioration of the person's state of health (§ 6.8).

3.25.1.3 The right to refuse treatment

If a legal representative refuses treatment for a patient who is unable to give informed consent, and doctors are of the opinion that such treatment is in the patient's best interests, they must submit an application to the relevant court to override the legal representative's refusal. Whilst this is being decided, only life-saving treatment can be provided (§ 6.6).

3.25.1.4 The right to withdraw consent

Any person who gave valid informed consent can freely withdraw it at any time (§ 6.7).

3.25.1.5 Consent to innovative treatment and participation in clinical teaching

Consent to participation in clinical teaching is perhaps what is meant by § 11.8 (e) which states that every person has the right to decide whether to take part in education.

3.25.1.6 Consent to blood donation

A blood donation (for the purposes of transfusion and the preparation of medications for transfusion) can only be made by a person who is over 18 years of age (§ 39.1) and fully capable of executing legal acts specified in § 39.2.

3.25.1.7 Consent to the donation of organs and/or human tissue

Paragraph 11.8 (f) grants people the right to refuse the removal and transfer of organs, tissue or cells after death.

Chapter 2 of part 4 of the Act on Healthcare deals with the removal, conservation and transfer of organs, tissue and cells. Living donors must be fully capable of executing legal acts and have given written informed consent. A person who is incapable of giving informed consent can become a donor provided that informed consent is given by his/her legal representative subject to the following conditions:

- a. The removal relates to regenerative tissue.
- b. A suitable donor capable of giving informed consent is not available.
- c. The potential recipient is a brother or a sister of the donor.
- d. The donation has a life-saving potential for the recipient (§ 36.2-d).

With regard to the removal of organs, tissue and cells after a person's death, this is permitted unless before dying the person made a written declaration disapproving of such an intervention. For people who are unable to object to such removal of organs, tissue and cells, their legal representative may make a written declaration on their behalf during their lifetime (§ 37.2).

Disapproval can be withdrawn at any time. Statements of disapproval must have a certified signature and be sent to the registry of persons declaring their disapproval with the post-mortem removal of their organs, tissue and cells, which is maintained by the Ministry of Health.

3.25.1.8 Consent to biomedical research

According to § 11.8 (e), every person is entitled to decide whether or not to take part in educational or biomedical research.

Chapter 1 of part 4 of the Act on Healthcare is dedicated to the issue of biomedical research. Such research cannot be carried out on a person who has been involuntarily interned. Otherwise, the following provisions apply (§ 32):

"(1) Medical indication based research with participation of a person incapable of giving an informed approval can be performed only in case that

(a) the research with comparable effectiveness cannot be performed with the participation of a person capable to give an informed approval,

(b) the person was informed about this research and about his/her rights and legal measures for their protection in a way adequate to his/her health condition and mental abilities,

(c) the person does not express evident disapproval with his/her participation in this research in a way adequate to his/her abilities to express disapproval regarding his/her physical and mental condition.

(2) Research without medical indication with participation of the person incapable of giving an informed approval can be exceptionally performed in the case that, besides conditions as per subsection 1, the following conditions are met:

(a) the objective of the research is to achieve results bringing benefit for other persons in the same or similar condition, suffering from the same or similar illness or handicap,

b) the research represents for the participant only

1. a risk that according to the current state of scientific knowledge constitutes only low and short-term negative influence on the health condition of the research participant (hereinafter "minor risk") or

2. a burden with only a low and short-term inconvenience (hereinafter "minor burden").

(3) Bio-medical research with the participation of a person incapable of giving an informed approval can only be performed on the basis of an informed approval of the legal representative of the future research participant."

3.25.2 Advance directives

According to Defloor et al. (2008), there is no legislation in the Slovak Republic covering previously expressed wishes.

3.25.3 Access to information/diagnosis

3.25.3.1 The right to be informed

Doctors must provide information on the purpose, nature, impact and risks of health-care provision, as well as on proposed alternative provisions and on the risks of rejecting healthcare. This information must be provided to the patient or another designated person. It should be given to the legal representative or tutor of people with incapacity. The information should be provided in a way that is comprehensible and appropriate to the person's intellectual level and health condition. The person should be given enough time to be able to give informed consent (§ 6.1-6.2).

3.25.3.2 Access to medical records

Part 3 of the Act on Healthcare deals with medical records. Medical records may be in written or electronic form. Anyone handling medical records is obliged to ensure that

they are treated with confidentiality and to protect them against loss or abuse. The patient (or his/her legal representative in the case of incapacity) has the right to examine his/her medical record and to make excerpts or copies. Doctors can refuse access to medical records to patients receiving psychiatric care if they believe that this would negatively affect their treatment. According to paragraph 25.1, the patient, his/her legal representative and/or a person previously appointed by means of a power of attorney are entitled to access the patient's medical file (to the extent determined by the power of attorney for the latter).

3.25.3.3 The right to designate another person to be informed on one's behalf

According to § 6.1-a, information must be provided to the patient or moreover to another person determined by the patient.

3.25.3.4 The doctor's right to withhold information

Paragraph 25.3 of the Act on Healthcare refers to the right to withhold access to the medical file but only in the domain of psychiatry or in the domain of clinical psychology and only if this would negatively affect the patient's treatment

3.25.3.5 The right to refuse information

Whoever has the right to be informed also has the right to refuse to be informed. A written record of such refusal must be made (§ 6.3).

3.25.3.6 Confidentiality/disclosure of information to other people

Patients have the right to confidentiality with regard to all information regarding their health condition and circumstances related to their health condition. Attending physicians and other healthcare professionals must have access to medical files to the extent that this is necessary (§ 22.3) and so must an inspector doctor from a pertinent health insurance, the Surveillance Authority, a court advisor in the case of criminal proceedings, a health insurance company inspecting the provision of healthcare linked to insurance, and professional organisations inspecting medical profession performance (§ 25.1).

3.25.4 End-of-life care and issues

3.25.4.1 Palliative care

According to § 11.8-h of the Act on Healthcare, every person is entitled to palliative care, as well as a humane, ethical and dignified approach from healthcare professionals (§ 11.8-i).

3.25.4.2 Euthanasia

There is no legislation directly concerning euthanasia in the Slovak Republic. However, the Ethical Code of the Slovak Chamber of Physicians prohibits it. This Code is, in the form of an appendix, part of Act No. 219/2002 Coll. on Profession of Physician, the Slovak Chamber of Physicians, Profession of Dentist, the Slovak Chamber of Dentists and amending and supplementing certain other acts (Council of Europe, 2003).

3.25.4.3 Assisted suicide

Assisted suicide is considered a serious criminal act according to § 230 of the Penal Law No. 141/1961 (as later amended) (Council of Europe, 2003).

3.25.4.4 Non assistance to a person in danger

Paragraph 11 (11) of the Act on Healthcare states that every person is obliged to provide or mediate necessary help to anyone in danger of death or anyone showing severe health damage unless one's own life or health would be severely endangered by such help.

3.25.4.5 Murder

Other legal provisions can be found in the Penal Law (Law No. 141/1961 as later amended). Under this law (paragraph § 219), euthanasia would be considered as the taking of an innocent human life (i.e. as murder) and/or as not providing necessary professional (life-saving) help, thereby failing to honour important professional obligations on the part of the physician or other health professional (§ 224) (Council of Europe, 2003).

3.25.5 Bibliography

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3.26 Slovenia

3.26.1 Consent

3.26.1.1 Consent to medical treatment

According to the Human Rights Ombudsman of the Republic of Slovenia, a doctor may only carry out a medical intervention on the basis of the patient's free consent following an explanation. However, there are exceptions where consent is not required. For example, article 51 (3) (Right to Healthcare) of the Constitution states:

"No one may be compelled to undergo medical treatment except in cases provided by law."

In August 2008 the Law on Mental Health was passed. This law permits referral and acceptance for treatment in a psychiatric hospital on the following conditions: with the consent of the patient (article 36-38), without the consent of the patient subject to a decision by a court of law (article 40-52) and without the consent of the patient in urgent cases (article 53-67).

Articles 19 to 25 of the Act on Patients Rights of 2008 address the issue of informed consent (hence covering both prior information and subsequent consent). It is forbidden to administer any treatment or healthcare to a person with disposing capacity unless he/she has given free and wilful consent after having received appropriate information. In some cases (depending on the type of proposed treatment) written consent may be required.

Consent is also covered by article 47 of the Law on Medical Practice which states that the patient or his/her guardian must consent to every medical practice (Trontelj and Korošec, 2003).

3.26.1.2 Consent for people unable to express their will

If a person lacks the capacity to consent the doctor can provide non-essential medical treatment provided that he/she does not or could not know that the patient or his/her authorised representative is opposed to the treatment. This would also be the case if the doctor considered treatment to be in the best interests of the patient but was unable to obtain consent within a reasonable amount of time (article 29 of the Act on Patients Rights) (Žnidaršič Skubic, 2008).

Article 37 of the Act on Patients Rights covers consent in the case of incapacity. If the patient's inability to consent is linked to his/her mental health condition, a legal representative must consent on his/her behalf. If the patient does not have a legal representative, steps must be taken to have one appointed. Meanwhile, the right to consent or refuse treatment on his/her behalf is granted to the following people (provided that they are of legal age and have full disposing capacity) in the following order: 1. spouse or partner (in case of civil union), 2. children or adopted children, 3. parents or foster parents, 4.

brothers or sisters, 5. grandparents, 6. grandchildren. These people cannot refuse emergency treatment. If they refuse consent, the doctor can decide on the patient's behalf, based on all opinions received and based on his/her assessment of the patient's best interests (Žnidaršič Skubic, 2008).

Patients may appoint a person to consent or refuse treatment on their behalf in the event that they are one day unable to do so themselves (art. 32-34 of the Act on Patients Rights). This advance appointment must be made in writing whilst the person has full disposing capacity. Similarly, the patient can exclude in advance someone who would normally have the right to consent or refuse consent on his/her behalf. Such information is recorded on the patient's health card or in his/her medical file (Žnidaršič Skubic, 2008)

3.26.1.3 Consent in case of emergency

According to article 28 of the Act on Patients Rights, emergency medical treatment can be administered to a person lacking capacity without his/her consent (Žnidaršič Skubic, 2008).

3.26.1.4 The right to refuse treatment or withdraw consent

According to article 31 of the Act on Patients Rights, patients with full disposing capacity can refuse treatment or withdraw consent at any time. However, the doctor must try to persuade the patient to accept treatment if he/she considers that the decision is not in the patient's best interests and could threaten the life of the patient or of other people. The doctor may even consult the patient's family or recommend that the patient seeks a second opinion (Žnidaršič Skubic, 2008).

3.26.1.5 Consent to innovative treatment

Article 3 of the Code of Medical Deontology of Slovenia states that doctors should only use therapeutic methods that have a scientific basis and have been accepted by the profession. It is further stated in article 14 that whilst they are free to select their methods and ways of healing, they must follow the latest achievements in medical science (Premik, undated).

3.26.1.6 Consent to the donation of organs and/or human tissue

The Law on Transplantation of Parts of Human Body for Therapeutic Purposes addresses the issue of organ transplantation. The removal of organs would be considered unlawful if the deceased person or close relations had refused this at the time of the removal. The Penal Code (article 191) addresses the issue of the removal of body parts, the implantation of such parts, the removal of such parts before legal confirmation of death or without having obtained prior consent of the donor or recipient and if dealing in body parts for money occurred (Trontelj and Korošec, 2003).

3.26.1.7 Consent to participation in scientific research and clinical trials

According to the EFGCP (2008), the regulations applying to clinical trials on investigational medicinal products are:

- Drug Act (Official gazette, No. 31/06) and Bylaw on Clinical Trials (Official gazette, No. 54/06), which is the Slovenian Directive on Clinical Drug Testing based on Directive 2001/20/EC.
- The Code of Medical Deontology of Slovenia.
- The Oviedo Convention.

Articles 47-50 of the Slovenian Code of Medical Deontology also contain provisions on the ethical conduct of biomedical research on human subjects (Trontelj and Korošec, 2003).

3.26.2 Advance directives and healthcare proxies

3.26.2.1 The legal status of advance directives in Slovenia

As explained in the next subsection, it is possible the patient to appoint (in advance of incapacity) a person to consent to or refuse treatment on one's behalf and also to state which person or people should not have such a right.

Article 34 of the Act on Patients Rights permits a person with full disposing capacity to state in writing his/her will regarding the rejection of treatment should he/she ever be incapable of expressing his/her will on this issue (i.e. an advance directive).

3.26.2.2 Conditions surrounding the writing, validity and registering of an advance directive

There is a special form for recording future wishes regarding the acceptance or refusal of treatment. In this form, it must be stated that the person making the advance directive has full disposing capacity and is of legal age. It must be signed by the person making the advance directive and contain details of his/her doctor and authorised health representative. An advance directive is valid for five years from the date of signature. Details of the patient's wishes are added to his/her medical card or main medical file.

3.26.2.3 Obligation to comply with instructions contained in an advance directive

Depending on the person's situation/condition at the time that the treatment is proposed, these wishes will be considered either binding or merely advisory.

A patient's previously expressed wishes would be considered binding if:

"he/she should suffer from grave illness, which given the ability of modern medicine would lead to death in a short period of time in spite of medical treatment or medical care, or for which treatment or care would not lead to an improvement in health or the alleviation of his/her suffering but rather only to the prolonging of his/her life."

A patient's previously expressed wishes would be considered by the doctor and guide him/her in deciding on a course of action if:

"the patient's life "would be prolonged by medical treatment or care, but he/she would end up being in a state where, due to the graveness of his/her disability, he/

she would lose physical and mental ability to take care of himself/herself." (Žnidaršič Skubic, 2008)

Previously expressed wishes might not be considered if there are reasonable grounds to believe that the patient would have retracted his/her wishes.

3.26.2.4 Amending, renewing and cancelling advance directives

An advance directive can be withdrawn by the patient at any time. The withdrawal must be in writing. It is not clear whether the patient has to have full disposing capacity to do this.

3.26.3 Access to information/diagnosis

3.26.3.1 The right to be informed

Article 20 of the Act on Patients Rights states covers the necessity for patients to be informed of their medical condition, the likely course and consequences of their condition, the purpose, type and manner of treatment, the likelihood of success and the likely outcome of proposed treatments. This is part of the process of obtaining informed consent. Such information must be provided in a way that is adapted to the patient's ability to understand and should be presented in a timely, considerate and comprehensive manner (Žnidaršič Skubic, 2008).

3.26.3.2 Access to medical records

Patients have the right to access their medical file and take notes on the condition that a doctor or healthcare worker is present. People who have the right to decide on the patient's behalf may also have access to the medical file insofar as this relates to a decision they need to make. This includes people who have been given written authorization by a patient with full disposing capacity provided that they also have full disposing capacity and are of legal age (art. 41-42 of the Act on Patients Rights). Patients can also name people who should not be granted access to their medical file.

Article 42 of the Act on Patients Rights grants certain people the right to access a patient's file after his/her death. This includes the patient's spouse, cohabiting partner, same sex partner, children or adoptive children or if the patient does not have such relatives, then his/her parents. However, if any of the above-mentioned people want to be granted post-mortem access to the medical files covering the period leading up to the patient's death in which he/she lacked full disposing capacity, they must demonstrate legal grounds for this (Žnidaršič Skubic, 2008).

3.26.3.3 The right to appoint another person to be informed on one's behalf

As mentioned in the section on consent, patients may appoint a person to consent or refuse treatment on their behalf in the event that they are one day unable to do so themselves. This advance appointment must be made in writing whilst the person has full disposing capacity. Similarly, the patient can exclude in advance someone who would

normally have the right to consent or refuse consent on his/her behalf. Such information is recorded on the patient's health card or in his/her medical file (Žnidaršič Skubic, 2008).

3.26.3.4 The doctor's right to withhold information

Article 22 of the Act on Patients Rights authorises doctors to withhold information from patients about patients' state of health if they consider that such information could result in serious harm to a patient's health. The reason for withholding information must be recorded in the patient's medical file. However, the right to withhold information does not apply if patient has full disposing capacity and expressly requests such information. The issue of withholding information from patients is also addressed in the Code of Medical Deontology which states that providing information to a patient who is deeply stressed or suffering from other psychological conditions is not recommended if doing so would be likely to have a negative impact on treatment. The doctor must, however, notify the patient's relatives (Žnidaršič Skubic, 2008).

3.26.3.5 The patient's right to refuse information

Patients have the right to refuse information about their state of health unless the lack of such information would pose a serious health risk to other people. The decision not to be informed must be recorded in the patient's medical file in accordance with article 22 of the Act on Patients Rights (Žnidaršič Skubic, 2008).

3.26.3.6 Confidentiality/disclosure of information to other people

The Law on Medical Activity stipulates that medical information about patients must be kept in accordance with a special law but this special law has not yet been passed. Consequently, the Law on Medical Records (Official Gazette of the Socialist Federal Republic of Yugoslavia, No. 22/78 and 18/88) is still in force. This law requires that information about patients with mental disorders be kept in a separate record (Human Rights Ombudsman, 2007).

The protection of personal data is guaranteed by article 38 of the Constitution and by the Personal Data Protection Act which gives people the right to be informed about any personal data collected and to legal protection against the misuse of such personal data. Misuse of personal data is punishable under article 154 of the Penal Code by up to 2 years' imprisonment (Trontelj and Korošec, 2003).

Article 153 of the Penal Code deals with the unlawful disclosure of secrets. Prosecution is initiated subject to a private action. It states:

(1) Whoever unlawfully discloses a secret which he/she has become party to in his/her position as counsel for the defence, doctor, priest, social worker or psychologist or by way of performing any other profession shall be punished by a fine or sentenced to imprisonment for not more than one year.

(2) No penalty shall be imposed on persons who commit such acts from the preceding paragraph where the disclosure of a secret is made for the general good or for some other person's benefit, and where the good or benefit therein is greater than that of withholding the secret.

3.26.4 End-of-life care and issues

3.26.4.1 Euthanasia

According to the European Association for Palliative Care (2005), there are currently no initiatives in Slovenia seeking the legalisation of euthanasia or assisted suicide.

3.26.4.2 Assisted suicide

Article 131 of the Penal Code deals with solicitation to and assistance in suicide:

(1) Whoever intentionally solicits another person to kill him/herself or assists him/her in doing so, resulting in that person indeed committing suicide, shall be sentenced to imprisonment for not less than six months and not more than five years.

(2) Whoever commits the offence under the preceding paragraph against a minor above fourteen years of age or against a person whose ability to understand the meaning of his/her act or to control his/her conduct was substantially diminished shall be sentenced to imprisonment of not less than one and not more than ten years.

(3) In the event of the offence under the first paragraph of the present article being committed against a minor under fourteen years of age or against a person who was not capable of understanding the meaning of his/her act or of controlling his/her conduct shall be punished according to the prescription for murder.

(4) Whoever treats his subordinate or a person depending on him in a cruel or inhumane manner resulting in this person's suicide, shall be sentenced to imprisonment for not less than six months and not more than five years.

(5) Whoever, under particularly mitigating circumstances, assists another person to commit suicide, and if that person indeed commits suicide, shall be sentenced to imprisonment for not more than three years.

(6) If, relating to a criminal offence under the above paragraphs, the suicide has only been attempted, the Court may reduce the punishment of the perpetrator.

3.26.4.3 Non-assistance to a person in danger

According to Žnidaršič Skubic (2008), "if the doctor were to fail to administer medical treatment resulting in harm or even death, he/she would be liable for dereliction of assistance." Article 140 of the Penal Code states:

Whoever fails to render aid to another person in a life-threatening situation, even though s/he could have done so without danger to him/herself or to any third person, shall be sentenced to imprisonment for not more than one year.

3.26.4.4 Murder

Article 127 of the Penal Code, which deals with murder, states:

(1) Whoever takes the life of another human being shall be sentenced to imprisonment for not less than five years.

and adds:

(3) If the offence under the first paragraph of the present article has been committed in especially mitigating circumstances, the perpetrator shall be sentenced to imprisonment for not less than six months and not more than five years.

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3.27 Spain

3.27.1 Consent

3.27.1.1 Introduction

There are currently two laws in Spain governing healthcare and decision making: 1. the Basic Law 41/2002 on the Autonomy of the Patient and the Rights and Obligations with regard to Information and Clinical Documentation (the “Patients’ Rights Law”), which entered into force on 16 May 2003²¹, 2. the Convention on Human Rights and Biomedicine, Oviedo, April 1997 (ratified by Spain on 23 July 1999). The Patients’ Rights Law incorporates all the principles of the Convention on Human Rights and Biomedicine.

The Law 41/2002 is the basic legislation as established in article 149.1.1 and article 16 of the Constitution. The State and the autonomous regions are responsible for taking the necessary measures to ensure the effectiveness of this law.

This Law contains additional conditions and further provisions governing medical research projects. It is stated, “The norms of this law relative to welfare information, information on freedom of choice of doctor and centre, the informed consent of the patient and medical records, will also be applicable in the case of medical research, the processes of extracting and transplanting organs, human-assisted reproduction and in other areas which lack special regulation”.

The Law 41/2002 has also repealed important articles of the former General Health Law, as stipulated in the Unique Repealing Disposition: “Dispositions of equal or low status that are opposed to the provisions contained in the present law are repealed, namely, paragraphs 5, 6, 8, 9 and 11 of article 10, paragraph 4 of article 11, and article 61 of the General Health Law 14/1986”.

3.27.1.2 Consent to medical treatment

In the context of the Patients’ Rights Law (41/2002) two possibilities are envisaged:

1. When incapacity has not been declared (i.e. when there has been no declaration of judicial incapacity),
2. When incapacity has been declared (i.e. there has been a court ruling and guardianship measures established).

When the patient is unable to make decisions in the opinion of the treating doctor, or his/her physical or mental state does not permit him/her to manage his/her situation, but he/she does not have a legal representative, consent must be given by a relative or someone tied to him/her for de facto reasons.

According to article 9, paragraph 3, for patients who have been declared legally incapacitated, consent must be granted by a legal representative.

It is stated in article 8 that consent should be given orally but there are certain exceptions for which written consent is necessary. These include surgical interventions, invasive diagnostic and therapeutic procedures, and in general, procedures involving risk or having a known or predictable negative impact on the patient's health.

According to article 9, paragraph 2, physicians may carry out clinical interventions which are essential for the patient's health without the patient's consent if there is a risk to public health which has been established by law. Once measures have been initiated in accordance with Law 3/1986, the judicial authorities must be informed within 24 hours in order to arrange for compulsory internment.

3.27.1.3 Consent from incapacitated people who have been interned

In the case of people who have been involuntarily interned due to mental illness and who do not have the control over their revenue, the doctor must be vigilant of the tutors who are authorized to manage the income of the person who has been interned. However, the doctor must ensure that he/she does not recommend unnecessarily burdensome or dangerous examinations or treatment. He/she must also ensure that the patient does not run any unnecessary risk.

3.27.1.4 Consent in case of emergency

Consent is not needed in case of emergency or in situations involving a serious and immediate risk to a person's physical or psychological integrity if it is impossible to obtain the consent of the patient, of his/her relatives or of people tied to him/her for de facto reasons (article 9, paragraph 2 of the Patients' Rights Law, 41/2002).

3.27.1.5 The right to refuse consent

Refusal of consent is addressed in article 2, paragraphs 3 and 4 of the Patients' Rights Law (41/2002). Patients have the right to decide freely, after having received the appropriate information, between the clinical options available (art. 2, par. 3). Such refusal must, however, be made in writing (art. 2, par. 4).

3.27.1.6 The right to withdraw consent

Under the Patients Rights Law (41/2002), patients are free to withdraw consent or refuse treatment at any time but this must be recorded in writing (article 8, paragraph 5).

3.27.1.7 Consent to the donation of organs and/or human tissue

Articles 19 and 20 of the Convention on Human Rights and Biomedicine (Oviedo, 1997) address the issue of consent to the donation of organs and human tissue and are applicable in Spain. The relevant provisions are as follows:

Article 19 – General rule

1. *Removal of organs or tissue from a living person for transplantation purposes may be carried out solely for the therapeutic benefit of the recipient and where there is no suitable organ or tissue available from a deceased person and no other alternative therapeutic method of comparable effectiveness.*

2. *The necessary consent as provided for under Article 5 must have been given expressly and specifically either in written form or before an official body.*

Article 20 – Protection of persons not able to consent to organ removal

1. *No organ or tissue removal may be carried out on a person who does not have the capacity to consent under Article 5.*
2. *Exceptionally and under the protective conditions prescribed by law, the removal of regenerative tissue from a person who does not have the capacity to consent may be authorised provided the following conditions are met:*
 - I. *there is no compatible donor available who has the capacity to consent;*
 - II. *the recipient is a brother or sister of the donor;*
 - III. *the donation must have the potential to be life-saving for the recipient;*
 - IV. *the authorisation provided for under paragraphs 2 and 3 of Article 6 has been given specifically and in writing, in accordance with the law and with the approval of the competent body;*
 - V. *the potential donor concerned does not object.*

The Convention on Human Rights and Biomedicine also applies in the case of research, particularly articles 5 and 6 which cover informed consent, and article 17, which specifically addresses the protection of people who are unable to consent to research:

3.27.1.8 Consent to clinical trials

Article 9, paragraph 4 of the Patients' Rights Law (41/2002) covers consent to participation in clinical trials (amongst other things).

3.27.2 Advance directives

3.27.2.1 The legal status of advance directives in Spain

Advance directives have been legal in Spain since 14 November 2002. The Patients' Rights Law (41/2002), which is applicable throughout the whole of Spain, permits people to state their wishes with regard to medical treatment whilst they still have the capacity to do so. Article 11 also covers the possibility to express wishes concerning the disposal of the person's body and organs after death, and the appointment of a representative with responsibility to ensure that healthcare professionals comply with the person's previously expressed wishes.

3.27.2.2 Conditions surrounding the writing, validity and registering of an advance directive

In order to write a valid advance directive, a person must be at least 18 years of age, free from pressure and have the necessary capacity to do so. In Spain, everyone is presumed to have capacity unless proven otherwise by means of a legal procedure and declared by a court.

The document can be formalized by a notary but there is no mention of this in the law. Consequently, it seems that this is not necessary. If the document is nevertheless signed in the presence of a notary, the notary must confirm that the person has the necessary capacity to sign such a document.

In most of the autonomous communities advance directives are made either in the presence of a notary or privately with witnesses. These witnesses should be named in the document and should also sign the document. It is presumed that by signing the document they are also confirming that the person writing the advance directive has the capacity to do so. Two out of the three witnesses should not be family members or have any economic/business relationship with the person making the advance directive. In some autonomous communities, where very few advance directives are made, it is possible to just sign the document in front of a healthcare professional or the person who is in charge of the advance directives registry.

Several autonomous regions have advance directive registries, so people writing advance directives should ensure that they follow the formal procedure of the region in which they reside. Legislation is pending to create a national register for advance directives. This was foreseen in the Patients' Rights Law (41/2002) in which it was stated, "For the purpose of ensuring the effectiveness throughout the national territory of advance directives, expressed by patients and formalized in accordance with the respective laws of the autonomous regions, the Ministry of Health and Consumer Protection will create a national registry of advance directives which will be governed by the regulations previously determined by the Inter-territorial Council of the national health system."

The Law stipulates that every health service should set up a suitable procedure to ensure compliance with a person's previously expressed wishes (which should always be in writing). In order to be considered valid:

- advance directives should not contain instructions which are against the law;
- advance directives should not contain instructions which are contrary to "lex artis" or good medical practice;
- the actual circumstances or situation must correspond to that/those previously envisaged.

Advance directives are not limited to a set period of time.

3.27.2.3 What an advance directive can cover

The Basic Law 41/2002 does not specify what an advance directive can or cannot cover. It can therefore be presumed that it could cover:

- The treatment of medical conditions;
- The treatment of a psychiatric condition;
- Care and welfare decisions;

- Research;
- Basic care;
- Life-supporting treatment; and
- Life-saving treatment.

As stated earlier, an advance directive may be used to appoint a representative who will be consulted by the doctor and healthcare professionals, when appropriate, in order to ensure that the person's previously expressed wishes are respected.

3.27.2.4 Obligation to comply with instructions contained in an advance directive

With regard to the refusal of life-supporting and life-saving treatment, some lawyers point out that doctors are faced with the conflicting duty of complying with the patient's request and fulfilling their own obligation to preserve life and maintain health. However, the law states that doctors can only ignore instructions contained in an advance directive if the instructions are against the law, contrary to good medical practice or do not correspond to the situation previously envisaged. If a doctor fails to comply with instructions contained in an advance directive and cannot comply with the previously expressed wishes, he/she must state why the patient's instructions were ignored.

3.27.2.5 Amending, renewing and cancelling advance directives

Advance directives can be amended, renewed or cancelled at any time provided that the person has the necessary capacity to do so. This must be done in writing. Some people involve a notary when modifying or cancelling an advance directive. However, a person with incapacity cannot revoke an advance directive. In such cases, to the best of our understanding, the legal representative (i.e. the tutor) can try to revoke the advance directive with the prior approval of the public prosecutor and the approval of the relevant guardianship court. If a person made several advance directives, the most recent one would be the one considered valid.

3.27.3 Access to information/diagnosis

3.27.3.1 The right to be informed

The Patients' Rights Law contains detailed information on the obligation to provide information to patients. As a general rule, such information must be given orally (previously it had to also be given in written form). Health information to be provided is divided into two categories: 1. healthcare information and 2. epidemiological information.

1. According to article 4, patients have the right to know, for any intervention linked to their health, all available information, unless otherwise stated by law. Moreover, everyone has the right for his/her wish not to be informed to be respected. Information, that as a general rule is provided orally but included in the medical files, should at least cover the purpose and nature of each intervention, as well as its risks and its consequences.

2. According to article 6, citizens have the right to know about the health problems of the community when there is a risk to public health or their individual health. This information must be disseminated using the correct terms and in a way that is understandable and suited to the protection of health in accordance with the law.

The information must be honest and adapted to the particular needs of the person so as to help them make the necessary decisions freely. People with partial incapacity or under guardianship should also be informed in a way that is adapted to their ability to understand. In such cases, their legal representative must also be informed.

3.27.3.2 Access to medical files

Patients (or their duly accredited representatives) are entitled to access and receive a copy of their medical records at any time provided that this would not be prejudicial to the rights of a third party. This is regulated in articles 16, 17 and 18 of the Patients' Rights Law.

It is stated in article 16 that a medical record is intended primarily to ensure that appropriate care is provided to the patient. Healthcare professionals and centres responsible for the diagnosis or treatment of the patient must have access to medical records which are essential for the provision of the appropriate care. Other provisions of article 16 include:

Every centre will set up a procedure to ensure that professionals have at all times the possibility to access the case history of each of their patients.

Access to the case history for legal or epidemiological ends, for public health, or for research or teaching, is governed by the provisions of the Organic Law 15/1999, of the Protection of Information of Personal Character, and in the Law 14/1986 of General Health, and other norms applicable in each case. Access to the case history for these purposes requires that information permitting the personal identification of the patient be separated from those of a clinical or welfare character, so that as a general rule the anonymity of the patient is maintained, unless the patient has given his/her consent not to keep them separate. Another exception is the possible situation in which it is necessary to combine personal information with clinical or care information for a legal or court process. Access to the information and documents contained in the case history shall be strictly limited to the specific purposes for which it was obtained.

Administrative and management staff of healthcare centres shall only have access to the information in a case history that is related to their specific functions.

Properly accredited healthcare personnel who exercise the functions of examination, evaluation, accreditation and planning shall have access to case histories in the fulfilment of their functions of cross-checking the quality of the assistance provided, the respect of the rights of the patient or any other obligation of the centre regarding the patients and users or the healthcare administration.

Personnel who gain access to information in the case history of a patient in the exercise of his/her functions are bound to secrecy.

The autonomous regions will regulate the procedure so as to ensure regularity in access to and the use of the clinical data.

Article 17 deals with the conservation of medical files.

Healthcare centres are obliged to preserve medical files in such a way as to guarantee their correct maintenance and safety, even those not necessarily in the original format, in order to be able to provide due assistance to the patient for a period of time adapted to each case and for a minimum of five years from the date of discharge of every period of care.

Medical files will also be kept for legal purposes in accordance with current legislation and when there are epidemiological reasons for investigation or for the organization and functioning of the National Health System. They will be handled in such a way as to prevent the possible identification of the affected persons.

Under article 18, the right to access medical files is not applicable if it would be detrimental to third parties. Healthcare providers may refuse to grant patients access to the subjective comments that the former made.

3.27.3.3 The right to designate another person to be informed on one's behalf

The patient is entitled to permit other people to receive information. This is stated in article 5, paragraph 1 of the Patients' Right Law which identifies the patient as the person who has the right to have the information. People who are related to him/her or linked for de facto reasons may also be informed provided that the patient has given explicit or implied consent.

3.27.3.4 The doctor's right to withhold information

The withholding of health information, known as the "therapeutic exception" is covered by article 5 of the Patients' Rights Law. Therapeutic exception refers to the doctor's right to act without the prior consent of the patient, when there is reason to believe that the knowledge of his/her condition could seriously damage his/her health. In such cases, the necessary information shall be provided to the patient's relatives or to people who are related to him/her for de facto reasons.

3.27.3.5 The patient's right to refuse information

Under the Patients' Rights Law, patients have the right not to be informed. This is also covered in article 10, paragraph 2 of the Convention on Human Rights and Biomedicine (Oviedo, 1997) which states that every person shall be entitled to receive information about their health but that the wish not to be informed must be respected.

3.27.3.6 Confidentiality/disclosure of information to other people

The patient has the right to expect health centres to establish mechanisms to enable careful medical records to be kept. This is stated in articles 7 and 19 of the Patients' Rights Law (41/2002). The latter governs access to medical records by healthcare professionals and centres. However, it does not cover the right to privacy or the protection of the patient's private life. The right to privacy is covered by Title X of the Spanish Criminal Code and the Organic Law 1/1982 of 5 May on the civil protection of the right to honour, to personal and family privacy and to protection of one's own image. However, according to a study carried out by Pérez-Cárceles et al. (2005), 95.1% of doctors provided information to a patient's family and of those who did so, 35.3% did not obtain prior consent.

The processing of personal data is covered by the Organic Law of 15/1999, relating to the protection of personal data. This law regulates how personal data should be processed and who can do this.

According to article 18 of the Patients' Rights Law (41/2002), the medical records of a patient can be accessed by his/her relatives or by people linked for de facto reasons after the death of the patient unless the patient clearly expressed that such access was contrary to his/her will. In any case, access to the medical file by a third party, on the grounds of a presumed health risk, is limited to the relevant data. Information must not be provided which would affect the patient's privacy, contain subjective professional comments or be harmful to third parties.

3.27.4 Euthanasia/assisted suicide

3.27.4.1 Palliative care

The Patients' Rights Law (41/2002) covers the right to refuse interventions or treatments, which are not compulsory, provided that palliative care services exist. In case of disagreement, judges have to decide on the matter.

In the case of indirect euthanasia, understood as the application of medication to relieve pain but which may also hasten death, a debate has developed about the necessity to develop new concepts and revisit old ones, thereby adapting to new social demands, with terms such as palliative care.

3.27.4.2 Euthanasia

Prior to 1978, euthanasia in its various forms was considered under the Penal Code as murder or incitement to commit suicide.

Although such a crime may be considered comparable to murder, mitigating circumstances (such as being motivated by pity, compassion or mercy etc.) may result in a lower penalty than would normally be the case for alleged murder.

Since 1978, associations in favour of euthanasia have been pushing for specific legislation relating to euthanasia. During this period, issues such as the autonomy of the patient, human dignity and the prohibition of inhuman or degrading treatment has profoundly changed the ideology of the pro-euthanasia movement.

Nevertheless, whilst a debate has started in all social domains, the spotlight will undoubtedly be in the field of bioethics. As a result of these discussions proposals have been made for the legalization of euthanasia.

3.27.4.3 Assisted suicide

Article 27 of the Spanish Code of Deontology, which was written by the Spanish Medical Association, states:

The doctor has a duty to try to cure or improve the condition of the patient whenever possible. If not possible, he/she is obliged to take the appropriate measures to promote the well-being of the patient. If there is a possible risk of shortening the patient's life despite administering the correct dose of medication, the doctor should inform the closest relative of the patient and check whether they find this appropriate.

The doctor shall not undertake or pursue diagnostic or therapeutic treatment that is without hope, useless or futile. He/she must take into account the explicit will of the patient to refuse life prolonging the treatment and to die with dignity. When the patient's condition makes it impossible for him/her to take decisions, the doctor shall take into consideration and assess the previously expressed wishes of the patient and the opinion of other relevant people.

The doctor will never deliberately provoke the death of any patient, not even in case of express request on the part of the latter.

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3.28 Sweden

3.28.1 Consent

3.28.1.1 Consent to medical treatment

The issue of consent is addressed in paragraph 2a of the Health and Medical Services Act (1982:763) which states that "health and medical services shall be conducted so as to meet the requirements of good care" - one such requirement being the obligation to respect the patient's self determination and integrity. This article further stipulates that care and treatment shall as far as possible be designed and conducted in consultation with the patient.

According to Leenen et al. (1993), relatives are generally consulted but they do not have a specific right to consent to treatment on behalf of an incapacitated person. Consent can be obtained from a custodian who is responsible for ensuring that his/her ward receives the care that he/she needs. If this is not possible and the patient is unable to consent, the doctor must decide on the appropriate treatment in the light of medical science and proven experience. Patients who are subject to involuntary internment are consulted whenever possible during the period of care. However, questions concerning treatment are ultimately decided by the chief medical doctor of the unit in which the patient is being cared for.

Where appropriate, a patient's next of kin is also consulted. The significance of the next of kin (anhöriga) is somewhat unclear in that opinions often vary as to who is entitled to represent a patient (Leenen et al., 1993).

According to Karin Sparring Björkstén²² (1999), ECT can be given to people with dementia without their consent, but this is extremely rare as one of the consequences of ECT is memory loss.

3.28.1.2 Consent in case of emergency

People can also be treated without their consent in case of emergency.

3.28.1.3 Consent to research

The Swedish National Council on Medical Ethics is an advisory board to the Swedish Government on ethical issues which arise as a consequence of scientific and technological advances in medicine. The council analyses the issues from a broad national perspective.

In 2004, a new law was introduced in Sweden: The Act on the Ethical Review of Research Involving Humans (SFS 2003:460). It covers research on living persons, but it also covers such fields as research on the deceased, research based on biological material from people and research that deals with sensitive information about people including information regarding criminal offences.

There are six regional research ethics committees and one central ethics board. According to the law, these bodies are given detailed instructions regarding their work, i.e. what their duties consist of. This year, the Government is proposing to Parliament some revisions in the law with the aim of elucidating certain paragraphs.

The law contains extensive rules on information and consent. In principle, research involving living people requires that the person in question has been informed and has given his/her consent. In some cases, research can be carried out without consent from the person concerned if he or she suffers from a mental disorder or poor health. In these cases, close relatives or guardians should be consulted.

3.28.2 Access to information/diagnosis

3.28.2.1 The right to be informed

In accordance with the Health and Medical Services Act (SFS 1982:763) patients must be informed of their state of health and of the treatment methods available. If this information cannot be supplied to the patient, it must be supplied to a close relative. This obligation is echoed in chapter 2 paragraph 2 of the Health and Medical Personnel (Duties) Act (SFS 1998:531).

3.28.2.2 The doctor's right to withhold information

According to chapter 2 paragraph 8 of the Health and Medical Personnel (Duties) Act (SFS 1998:531), confidentiality of information also applies to the patient in that information about a patient's state of health may be withheld if it is felt that, bearing in mind the purpose of the care or treatment, it is highly important that it is not supplied to the patient.

3.28.2.3 Confidentiality/disclosure of information to other people

In the Health and Medical Personnel (Duties) Act (SFS 1998:531) it is stated that health professionals may not improperly divulge matters which come to their attention concerning the state of health or other personal matters of individuals. Provisions covering public health and medical care are also contained in the Secrecy Act (SFS 1980:100).

3.28.2.4 Confidentiality in the case of potential danger

If a person who possesses a firearm is admitted to hospital for the care of a mental disturbance and the doctor who is directly responsible for his/her care is of the opinion that he/she should not possess one, it is this doctor's responsibility to report the matter to the police (Arms Act (SFS 1996:67)).

3.28.3 End-of-life care and issues

3.28.3.1 Euthanasia/assisted suicide

The Swedish criminal code does not specifically deal with euthanasia.

3.28.3.2 Assisted suicide

A person who helps another to commit suicide or brings about his/her death can be faced with an accusation of murder or manslaughter. Please see below.

3.28.3.3 Murder

A person who helps another to commit suicide or brings about his/her death can be faced with an accusation of murder or manslaughter.

The relevant articles relating to murder and manslaughter can be found in Chapter 3 of the Swedish Criminal Code (SFS 1962:700):

Paragraph 1

Whoever causes the death of another person is guilty of murder and condemned to ten years' imprisonment or to life imprisonment.

Paragraph 2

If the crime mentioned in paragraph 1 is considered less serious as a result of particular circumstances or other factors, the sentence is that envisaged for involuntary (guilty) homicide, at least six and at most ten years' imprisonment.

In the Swedish criminal code, tribunals can, under certain circumstances, inflict sentences which are less severe than those foreseen by the law. In the case of murder or manslaughter, as well as in certain circumstances, the criminal code grants the tribunal discretionary power to determine the punishment. In particular, the judge can inflict a lighter sentence on a person, if the accused is motivated by profound human compassion. The relevant dispositions are covered in Chapter 29 of the Criminal Code which states:

Paragraph 1

In order to ensure a uniform administration of justice, punishment shall be determined within the framework of punishment applicable according to the crime or crimes altogether.

At the time of the determination of punishment, special attention should be paid to damage, violation or danger engendered by the act, to the perception of the accused or that which he/she should have, as well as his/her intentions or motives.

Paragraph 3

At the time of determining punishment, the following points must be borne in mind – besides those which apply to particular cases – as attenuating circumstances.

Was the criminal act provoked by the serious reprehensible behaviour of somebody?

Was the ability of the accused to control his/her actions seriously diminished due to mental disorder or a state of excitement or another cause?

Has the behaviour of the accused been clearly influenced by a developmental retardation, lack of experience or a diminished judgmental capacity?

Is the crime the result of a great compassion for another individual?

Lighter sentences than those foreseen for such crimes can be given in these circumstances.

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3.29 Switzerland

3.29.1 Consent

3.29.1.1 Consent to medical treatment

There is no patient law on federal level, but article 10 of the Swiss Constitution covers (amongst other things) the right to physical integrity. Article 28 of the Civil Code is also relevant to the issue of consent. It states that a person who suffers unlawful injury to his/her person can take the affair to court in order to obtain protection.

In several cantons, there are health laws covering the issue of consent but often they are only applicable in public establishments.

Article 1 of the guidelines of the Swiss Academy of Medical Sciences (SAMS) on the self-determination of patients states that it is forbidden to administer any medical act against the expressed will of a patient capable of discernment even if the patient's wishes do not seem to be in his/her best interests. Specific requests for treatment or care should only be accepted if they are in line with current medical practice. It is also stated that minors and people who are under tutorship may be capable of discernment when it comes to consenting to treatment.

3.29.1.2 Consent for people unable to express their will

If a person has not made an advance directive or appointed a healthcare proxy (known as a therapeutic representative), relatives might be consulted. At the moment, there are still different solutions in different cantons but with the new Law on the Protection of Adults (the "Erwachsenenschutzrecht"), which was adopted by the Parliament in December 2008 (but is not yet in force), there will be uniform rules.

Article 377, for example, stipulates that for treatment that was not determined in an advance directive, the doctor must draw up a treatment plan with the person authorized to represent the patient in medical matters. That person must be provided with all information pertinent to the proposed treatment. The doctor must nevertheless involve the patient in the decision-making process to the extent this is possible.

In article 378 the people who are authorized to consent or refuse treatment on behalf of the person with incapacity are listed in order of priority which is as follows:

1. The person designated in an advance directive or in an order/mandate linked to incapacity (mandate pour cause d'inaptitude)
2. The guardian (curateur) who has authorization to represent the person in medical matters
3. The spouse or registered partner if he/she is living with the person or provides regular personal assistance to him/her

4. The person's descendants if they provide regular personal assistance to him/her
5. The person's father and mother if they provide regular personal assistance to him/her
6. The person's brothers and sisters if they provide regular personal assistance to him/her

In the case of several representatives, the doctor can, in good faith, presume that each acts with the consent of the others. In the absence of an advance directive, representatives must decide in accordance with the person's presumed wishes and interests.

The guidelines on the medical treatment and care of persons with disability (2008) of the Swiss Academy of Medical Sciences (SAMS) distinguish between patients who have never had capacity and those who used to have capacity (articles 4.1 and 4.2). With regard to the latter, it is stated that their presumed wishes must be sought. This should include trying to find out if they ever expressed their wishes in writing (e.g. in an advance directive) and taking into consideration statements made by a person who was designated by them and granted authorisation to make medical decisions on their behalf (a therapeutic representative). Healthcare staff should also try to determine whether a patient made his/her wishes known in another way, through relatives for example. In principle, any presumed wishes of the patient expressed in any of the above-mentioned ways take precedence over any decision to the contrary made by a legal representative.

3.29.1.3 Consent in case of emergency

According to article 379 of the new Law on the Protection of Adults, in emergency situations, the doctor can treat patients who are incapable of discernment on the basis of their presumed will and best interests.

3.29.1.4 Special kinds of consent

At federal level, there are not yet laws specifically referring to consent to innovative treatment, participation in clinical teaching or the use of bodily substances. However, there will be a new article in the Constitution and a new law concerning research on human beings. This will determine under which circumstances people incapable of discernment can participate in research. However, nobody can do anything against the presumed will of a person (except in case of emergency) as this would be considered as bodily assault and would be punishable. The rules of the Academy of Doctors are applicable.

3.29.1.5 The right to refuse treatment

One possibility to refuse treatment is through an advance directive. Generally speaking, the patient's right to self-determination also covers the right to refuse treatment.

People who are allowed to decide on behalf of the patient also have the right to refuse treatment on his/her behalf.

3.29.1.6 Consent to the donation of organs and/or human tissue

The Federal Law on the Transplantation of Organs, Tissue and Cells of 8 October 2004 (Section 3, article 12) permits the donation of organs, tissue or cells from a living person on the following conditions:

1. the donor is an adult and capable of discernment;
2. he/she has given his/her informed consent in writing;
3. the donation would not result in any serious risk to his/her life or health;
4. the receiver cannot be treated by another therapeutic means of comparable efficacy.

However, it is stipulated in article 13 that a minor or incapable adult cannot donate tissue, organs or cells although in exceptional circumstances regenerative tissue or cells can be donated by a minor or incapable adult subject to the fulfilment of certain conditions. For incapable adults, the conditions which must be fulfilled, in addition to those stated in article 12, are as follows:

- the donation only represents a minimum risk or burden to the donor;
- no other capable adult donor is available;
- the receiver is the father, mother, a child, a brother or a sister of the donor;
- the donation could save the life of the receiver;
- the legal representative has given his/her informed consent in writing;
- there is no indication which might suggest that the incapable adult is opposed to the donation;
- an independent authority has given its authorisation.

Every effort must be made to inform incapable adult donors in the information process with the aim of obtaining their informed consent.

The above law only relates to donation for transplantation not for research. Donation for research will be covered by the Law on Research on Human Beings which will contain special rules for people who are incapable of discernment.

3.29.1.7 Consent to clinical trials

In Switzerland, there are specific regulations at federal level regulating the clinical trial of medicinal products. An Ethics Commission examines each project and the Swiss agency for the authorisation and supervision of therapeutic products (Swissmedic) is also involved.

3.29.1.8 Consent to research

There is as yet no law on clinical research at federal level. Research involving humans is mainly covered by cantonal law and where laws do exist, their scope, content and precision vary considerably from one canton to the next.

In September 2009, however, the parliament adopted a new article of the constitution concerning research on humans (“l’article constitutionnel relatif à la recherche sur l’être humain”). The administration is preparing the corresponding law (“loi fédérale relative à la recherche sur l’être humain (LRH)”).

According to article 118b of that law, research cannot be carried out on a person who has not given informed consent (or whose legally appointed representative has not given consent). Certain legal exceptions to the need for informed consent are possible but a refusal to take part must always be respected. The risks and burden of the study should not be disproportionate to the usefulness of the project. People with incapacity should only be involved in studies if it is not possible to use people with capacity instead. If the study is unlikely to bring personal benefit to people lacking capacity who are taking part, the risk and burden must be minimal.

The Swiss Alzheimer Association took part in the Consultation. As a result of the consultation process, the clause on forced research on people incapable of discernment was dropped. Switzerland seems to be following the rules of the Convention on Human Rights and Biomedicine of the Council of Europe.

3.29.2 Advance directives

3.29.2.1 The legal status of advance directives in Switzerland

In December 2008, the Swiss Parliament adopted the new Law on the Protection of Adults (“Erwachsenenschutzrecht” or “loi sur la protection de l’adulte”). However, this law is not yet in force (and perhaps will not be before 2013) which means that legally there is not yet a specific law relating to advance directives at federal level. However, in a lot of cantons (e.g. Argovia, Appenzell, Berne, Outer Rhodes, Geneva, Lucerne, Valais and Zurich), advance directives are covered by healthcare legislation.

The new law at federal level (i.e. the Law on the Protection of Adults) states that everyone can make an advance directive concerning the type of care that they would or would not like to receive in specific situations when they are no longer able to express their wishes.

In the same way, everyone can designate a person who will be responsible for making decisions on their behalf concerning the choice of care to be provided in these same circumstances.

Advance directives must be respected as long as they correspond to the current situation and there is no indication that the patient's will has changed.

Advance directives are also governed by laws relating to the protection of privacy and personal liberty (article 27/28 of the Swiss Civil Code and article 10 of the Constitution).

3.29.2.2 Conditions surrounding the writing, validity and registering of an advance directive

It is not necessary to have witnesses or to involve officials when writing an advance directive. The document must however be in writing or print and must be signed. Several organisations (e.g. Pro Senectute) have ready-made advance directives that people can use. Alzheimer Switzerland published in December 2007 an information sheet on this theme entitled "directives anticipées et représentant thérapeutique".

Capacity is presumed but in case of doubt, experts are called in to try to determine whether the author of the advance directive had the necessary capacity at the time the document was produced.

It is specified in the Law on the Protection of Adults that an advance directive must be sufficiently precise, correspond to the author's presumed wishes and be an expression of the author's free will. In addition, the appointment of a healthcare proxy should be publicly certified and the document deposited at an official organisation. There is no time limit on the duration of advance directives.

3.29.2.3 What an advance directive can cover

There are no conditions regarding the content of advance directives. They cannot, however, contain wishes or instructions that are against the law, e.g. for active euthanasia. Consent or refusal of life-supporting and/or life-saving treatment is possible.

Article 370 of the Law on the Protection of Adults allows for a competent adult to appoint in writing one or more people who in the event of his/her incapacity can consent to medical treatment on his/her behalf (i.e. a healthcare proxy).

Article 373 states that a person can write an advance directive covering the acceptance or refusal of medical treatment.

3.29.2.4 Obligation to comply with instructions contained in an advance directive

Even though advance directives currently have no legal basis at federal level, it is generally accepted that doctors should comply with instructions/wishes contained in an advance directive provided that the conditions for making a valid advance directive have been fulfilled.

According to article 372 of the Law on the Protection of Adults:

1. *When a doctor is treating a person who is incapable of discernment and does not know whether s/he has an advance directive, s/he must find out if one exists by consulting the patient's health insurance card. This does not apply in case of emergency.*
2. *S/he must respect the patient's advance directive unless it violates the law, or if there are serious doubts as to whether it represents the patient's free will or whether it corresponds to the his/her presumed wishes in the given situation.*
3. *S/he must record in the patient's medical file any reasons for failing to respect the advance directive.*

Article 373-1 further states that

Any relative of the patient can inform in writing the guardianship authority of the patient that:

1. *the advance directive has not been respected;*
2. *the patient's interests are or risk being compromised;*
3. *the advance directive does not represent the free will of the patient.*

Doctors are not obliged to comply with an advance directive if there are grounds to believe that the document no longer corresponds to the patient's wishes. This is difficult to determine once a person has lost capacity.

3.29.2.5 Amending, renewing and cancelling advance directives

An advance directive can be amended, renewed or cancelled at any time provided that the author still has the capacity of discernment.

3.29.2.6 Guidelines of the SAMS

The Swiss Academy of Medical Sciences (SAMS) has issued new guidelines on advance directives. For further details about these guidelines, please refer to: <http://www.samw.ch/fr/Ethique/Directives/actualite.html>

3.29.3 Access to information/diagnosis

3.29.3.1 The right to be informed

The patient has the right to be informed in a clear and appropriate manner about his/her state of health, about examinations and treatments that could be envisaged, about the consequences and possible risks that they may involve, about the prognosis and about the financial aspects of the treatment. If s/he is incapable of discernment, his/her legal or therapeutic representative or relatives must be informed. At federal level, there is no "direct legislation", but the basis for this right is article 28 of the Civil Code (protection of the person). There are also cantonal laws (e.g. Berne, Vaud, Zurich).

3.29.3.2 Access to medical files

The patient has the right to consult his/her medical file and to obtain explanations about the meaning of the information. Healthcare professionals can only withhold information in the form of personal notes or about other people. However, if the healthcare professional thinks that consulting the medical file could have serious consequences for the patient, s/he can request that the consultation take place in his/her presence or in the presence of another healthcare professional chosen by the patient.

3.29.3.3 The right to designate another person to be informed on one's behalf

Article 370 of the Law on the Protection of Adults allows for a competent adult to appoint in writing one or more people who in the event of his/her incapacity can consent to medical treatment on his/her behalf (i.e. a healthcare proxy). However, this has not yet come into force.

If somebody designates a trusted person or healthcare representative ("une personne de confiance ou représentant thérapeutique"), this person must be informed.

3.29.3.4 The doctor's right to withhold information

The doctor is entitled to limit or even withhold information in either of the following cases:

- If the patient clearly refuses to be informed, e.g. if s/he does not want to know if s/he has an incurable illness. In such cases, the refusal of information does not imply a refusal of care.
- In emergencies, the information can be given later.

There is no federal law governing the right to withhold information but there are some cantonal laws, e.g. in Berne and there is the jurisprudence of the Swiss Federal Court (federal tribunal) which is very important.

3.29.3.5 The patient's right to refuse information

The patient's right to refuse information or not be informed is based on his/her right to self-determination (based on articles 27 and 28 of the Civil Code).

3.29.3.6 Confidentiality/disclosure of information to other people

The Federal Law on the Protection of Data (LPD) of 19 June 1992, which came into force on 1 July 1993, covers all information relating to a specific person and the handling of such information by private persons and federal organisations. Private persons should be understood as including not only independent doctors but also psychologists, psychotherapists, personnel in private clinics, insurance agents and health insurance companies. Insurance agents and health insurance companies which are active in the domain of the obligatory health insurance are classed as federal organisations.

Certain information is considered sensitive and requires special protection. This includes medical notes about the progress of treatment, descriptions of symptoms, diagnoses, prescriptions, reactions, results of analyses or X-rays.

3.29.4 End-of-life care and issues

3.29.4.1 Palliative care

There is no law on palliative care but the Swiss Academy of Medical Sciences has produced guidelines. An English version of these guidelines can be found at: www.samw.ch/docs/Richtlinien/e_RL_PallCareDef23_05_06.pdf

Awareness of this problem has been increasing and new surveys about the availability of palliative care in Switzerland have been carried out.

3.29.4.2 Special leave for carers in paid employment (to care for a terminally ill person)

Legislation is very restrictive and carers are dependent on the generosity of their employer. A study about this problem, entitled "Work and Care", has been carried out. Alzheimer Switzerland participated in this study.

3.29.4.3 Euthanasia

Administering medication (e.g. morphine) to relieve suffering which may also have the secondary effect of shortening a patient's life (sometimes known as the double effect) is generally regarded as permissible. This is reflected in the guidelines of the Swiss Academy of Medical Sciences (according to the Federal Office of Justice, 2006).

There are no specific legal provisions governing passive euthanasia, e.g. the renunciation or discontinuation of life-prolonging measures. This is also mentioned in the guidelines of the Swiss Academy of Medical Sciences (SAMS guidelines).

3.29.4.4 Assisted suicide

Assisted suicide involves enabling a person (who wishes to commit suicide) to obtain a lethal substance, which that person then takes themselves without any external assistance. Contrary to popular belief, assisted suicide is punishable under Swiss law but only if the person who is assisting is motivated by self-serving ends. If so, according to Article 115 of the Swiss Penal Code, that person could be punished by strict-regime imprisonment for up to five years, or by ordinary imprisonment.

Certain organisations, such as EXIT, offer assistance to people wishing to commit suicide within the confines of the law. In order to avoid prosecution, they must be able to prove that they did not have any self-service motive. It is stipulated in the SAMS guidelines that assisted suicide is not a part of a physician's activity.

The above information was taken from the website of the Federal Office of Justice (2006).

3.29.4.5 Non-assistance to a person in danger

Non-assistance to a person in danger is dealt with in article 127 of the Penal Code. It states that a person who does not provide assistance to a person who is dependent on him/her and who is not capable of protecting him/herself, may be punished by up to 5 years' imprisonment or a fine. The same applies if someone prevents another person from providing such assistance.

3.29.4.6 Murder and murder at the request of the victim

The deliberate killing by a doctor or third party of another person (e.g. by an injection resulting in death) would be punishable under article 111 (murder), article 114 (mercy killing on request) or article 113 (manslaughter) of the Swiss Penal Code.

3.29.5 Bibliography

Federal Office of Justice website – accessed on 15 March 2007: http://www.ofj.admin.ch/bj/en/home/themen/gesellschaft/gesetzgebung/sterbehilfe/formen_der_sterbehilfe.html

Federal Office of Health website: <http://www.bag.admin.ch/themen/medizin/index.html?lang=fr>

Swiss Academy of Medical Sciences, Guidelines on palliative care. English version can be found at: www.samw.ch/docs/Richtlinien/e_RL_PallCareDef23_05_06.pdf

3.30 Turkey

3.30.1 Consent

In this section, the Regulations of 1998 of the Ministry of Health on Patients' Rights (1 August 1998, No. 23420) will be referred to as the Patients' Rights Act.

3.30.1.1 Consent within the healthcare contract

Consent is covered in two places in the Patients' Rights Act. Firstly, in article 5(d)

"except in cases of medical necessity or in cases provided for by law, there shall be no infringement of the physical integrity of a person or of other rights inherent in the individual without the consent of the person concerned."

and secondly, in article 22 which states:

"No person may be subjected to a medical procedure without his/her consent or in a manner that is not in keeping with the consent that s/he has given, subject to exceptions laid down by law."

3.30.1.2 Consent in case of emergency

This is covered by article 5(d) of the Patients' Rights Act and also in article 22 which states that a medical procedure can be carried out at the request of the State Prosecutor in cases where delay would be detrimental.

3.30.1.3 Consent to non-conventional treatment

Patients are entitled to receive diagnosis, treatment and care that is in keeping with modern science and technological requirements. It is prohibited to give a diagnosis or administer treatment that runs counter to the principles of medicine or the legal provisions governing medicine, which is of doubtful quality (article 11 of the Patients' Rights Act). Whilst this article is not directly about consent, it seems that non-conventional treatment is not allowed irrespective of whether a person consented to it or not.

3.30.1.4 Consent to clinical trials

This is covered by article 36 of the Patients' Rights Act.

3.30.1.5 Consent to research

Under article 5(e) of the Patients' Rights Act, no one may be subjected to medical research without his/her consent or an authorization from the Ministry.

Article 17 of the Constitution of the Republic of Turkey also states:

"The physical integrity of the individual shall not be violated except under medical necessity and in cases prescribed by law; and shall not be subjected to scientific or medical experiments without his or her consent."

There is a section (in Chapter VI Medical Research in the Patients' Rights Act) on "modalities and forms of consent" and one on "cases involving minors and incompetent persons".

3.30.2 Advance directives

There are no legal regulations governing the use of advance directives in Turkey.

3.30.3 Access to information/diagnosis

Unless otherwise stated, the articles quoted in this subsection are from the Patients' Rights Act of 1998.

3.30.3.1 The right to be informed

Under article 15, patients are entitled to request to be informed (either orally or in writing) about their state of health, medical treatment envisaged, foreseeable advantages and disadvantages, possible alternative treatment, the possible consequences of not accepting treatment, and his/her prognosis.

If the person is under guardianship, his/her guardian or legal representative may request such information.

Article 18 covers the need to provide information to the patient in a comprehensible manner taking into account his/her physical state and with due consideration for his/her feelings. There is no mention of his/her mental state.

3.30.3.2 Access to medical records

Article 16 states:

"The patient may check, directly or through the intermediary of his/her agent or legal representative, his/her medical file and the data contained therein and make a copy thereof. The said data may only concern the patient's treatment."

3.30.3.3 The right to designate another person to be informed on one's behalf

Patients may authorise another person to be informed on their behalf. If necessary, the power of attorney may be requested. Please also see "access to medical records" below.

3.30.3.4 The doctor's right to withhold information

Doctors have the right to withhold a serious prognosis/diagnosis if revealing such information would be likely to jeopardize the patient's mental state, aggravate his/her condition. A diagnosis that does not result in treatment may be withheld by a doctor or revealed with considerable tact. Such a diagnosis is nevertheless communicated to the patient's family provided that the patient did not personally express in advance an objection to this (article 19).

3.30.3.5 The patient's right to refuse information

Patients have the right to refuse information about their state of health and/or that such information be communicated to their family or associates (except in certain cases and for certain diseases as laid down by law) (article 20).

3.30.3.6 Confidentiality/disclosure of information to other people

Patients have the right to request that their privacy be respected and for their request to be respected. Every medical procedure must be carried out in such a way as to respect the patient's privacy. However, a patient may request the presence of a "close associate" as long as this would not interfere with the treatment and may also request that people not directly involved in his/her treatment are not present. Confidentiality shall be maintained even after the death of the patient (article 21).

3.30.4 End-of-life care and issues

3.30.4.1 Euthanasia/murder at the request of the victim

It is stated in the Patients' Rights Act that euthanasia shall be prohibited. More precisely, article 13 states:

"It shall be prohibited to take life, by medical methods or in any other manner whatsoever. The taking of a person's life shall not be permitted, either at his request or at the request of another person".

3.30.4.2 Non-assistance to a person in danger

Failure to render assistance to an old, disabled or injured person or to notify the relevant authorities is punishable by up to one year's imprisonment or a fine. If failure to provide assistance or to contact the relevant authorities results in the person's death, the sentence is from one to three years' imprisonment (article 98 of the Turkish Penal Code).

3.30.4.3 Homicide/murder

Intentional harm resulting in the death of the victim is punishable by 8 to 16 years' imprisonment (article 87.4 of the Turkish Penal Code).

3.30.5 Bibliography

Ornek Buken, N. and Buken, E. (2004), Patient's Rights in Turkey, <http://www.ishim.net/ishimj/5/10.pdf> (accessed online on 7 July 2009)

3.31 United Kingdom - England

3.31.1 Consent

3.31.1.1 Consent to medical treatment

A patient's ability to consent to treatment must be assessed each time treatment is necessary. Nobody can consent to treatment on behalf of a person who is either temporarily or permanently incapable of doing so (except in accordance with the provisions laid down in the Mental Capacity Act 2005).

For example, under the Mental Capacity Act 2005, if a personal welfare LPA (lasting power of attorney) has been appointed, s/he has the power to make decisions about health and personal welfare including day-to-day care and medical treatment. The personal welfare LPA only takes effect when the donor (the person who appointed the LPA) lacks capacity.

In certain cases, treatment can be given without a person's consent. The justification for doing this is that the treatment is "necessary". The concept of "necessity" does not only apply in emergency situations but can justify routine treatment and even simple care. It is a doctor's common law duty to give treatment to an incapacitated person if this would improve or prevent a deterioration of the patient's health, provided that it is clear that it is in the patient's best interests. The Mental Capacity Act 2005 states how a person's best interests should be determined. In certain cases, the courts must intervene.

3.31.1.2 Consent of people who have been detained under the Mental Health Act 2007

People who have been detained according to the provisions of the Mental Health Act 2007 may be given medical treatment for the mental disorder from which they are suffering without their consent. This does not apply to any medical treatment for mental disorder which involves a surgical operation for destroying brain tissue or for destroying the functioning of brain tissue. For such treatment, the patient's consent must be obtained and can be withdrawn at any time. In addition, a registered medical practitioner appointed for this purpose by the Secretary of State and two other persons appointed for the purpose must certify in writing that the patient is capable of understanding the nature, purpose and likely effects of the treatment in question and has consented to it. Furthermore, the registered medical practitioner must certify in writing that as the treatment is likely to alleviate or prevent a deterioration of the patient's conditions, it should be given.

3.31.1.3 Consent in case of emergency

Consent from the patient is not necessary if the treatment is necessary to save the patient's life, prevent a serious deterioration of his/her health, alleviate serious suffering by the patient or if it represents the minimum interference necessary to prevent the patient from behaving violently or being a danger to him/herself or others. However, if a

legally binding advance decision has been made by the patient which directs that they would not want certain interventions, it is possible that a doctor would have to abide by its terms (see below for further information on advance decisions).

3.31.1.4 The right to refuse treatment

Everyone has the right to refuse treatment as long as they have capacity *and* are not under a section.

3.31.1.5 Consent to the donation of organs and/or human tissue

Under existing common law a bone marrow donation cannot be taken from an adult who is incapable of giving consent until the individual circumstances of the case have been discussed in court.

Where an adult has, whilst alive and competent, consented to brain donation (or appointed a nominated representative in writing in the presence of a witness to act on their behalf in this regard), for the use or storage of tissue for research, then that consent is sufficient for the activity to be lawful. In the case where no such consent exists, and the deceased adult has not specifically refused brain donation for research (either themselves or through a nominated representative appointed in writing to act on their behalf), those close to them (persons in qualifying relationship) can be asked to take this decision. There is a ranking intended to help those seeking consent to know who to approach and in what order if someone is not available in reasonable time after death (spouse/partner, then parent/child, then brother/sister, and so on). The Human Tissue Authority Code of Practice on Consent gives further information on nominated representatives and persons in a qualifying relationship (Alzheimer's Society, 2009).

3.31.1.6 Consent to clinical trials

The following section also applies to clinical trials.

3.31.1.7 Consent to take part in research²³

All research projects must be approved by the local research ethics committee (LREC). Competent adults should normally consent to both therapeutic and non-therapeutic research. However, the Mental Capacity Act of 2005 contains a section on research in which it is stated that a person who is unable to consent may participate in research projects provided that certain conditions are fulfilled. One condition is that the researcher identifies a carer (or another person interested in the person's welfare) who can advise as to whether the person with incapacity should take part in the research and what the wishes and feelings of the person with incapacity about participation would be likely to be if they had the necessary capacity to decide. Elsewhere in the Act, it is stated that in determining what is in a person's best interests, people must consider the person's past and present wishes and feelings and, in particular, any relevant written statement made when the person had capacity.

With regard to therapeutic and non-therapeutic research, section 31 (2) of the Mental Capacity Act states that to obtain approval from the appropriate body, the proposed research must be connected with (a) an impairing condition affecting the person with incapacity or (b) its treatment. In the terms of the act an "Impairing condition means a condition which is (or may be) attributable to, or which causes or contributes to (or may cause or contribute to), the impairment of, or disturbance in the functioning of, the mind or brain."

Furthermore, there must be reasonable grounds for believing that research of comparable effectiveness cannot be carried out if the project has to be confined to, or relate only to, persons who have capacity to consent to taking part in it.

Section 31 (5) states that the research must:

- (a) *have the potential to benefit the person with incapacity without imposing on them a burden that is disproportionate to the potential benefit to them, or*
- (b) *be intended to provide knowledge of the causes or treatment of, or of the care of persons affected by, the same or a similar condition.*

If the research falls within paragraph (b) of subsection (5) but not within paragraph (a), there must be reasonable grounds for believing:

- (a) *that the risk to the person with incapacity from taking part in the project is likely to be negligible, and*
- (b) *that anything done to, or in relation to, the person with incapacity will not -*
 - (i) *interfere with their freedom of action or privacy in a significant way, or*
 - (ii) *be unduly invasive or restrictive.*

Finally, there must be reasonable arrangements in place for ensuring that carers and significant others are consulted and that additional safeguards covering withdrawal from the research are in place.

3.31.2 Advance decisions/living wills

3.31.2.1 The legal status of advance decisions in England and Wales

Until recently, no one was legally authorised to consent or refuse particular medical treatment on behalf of an adult lacking capacity and there was no statute directly governing the use of advance decisions in the United Kingdom. Advance decisions had legal status in England and Wales under Common Law but an advance decision concerning a person's treatment for mental disorder would not be legally binding if the person who made it was subject to compulsory powers under the Mental Health Act 1983. However, an advance decision concerning a physical disorder unrelated to the mental disorder would not be affected by a person's detention under the Mental Health Act.

In April 2005, the Mental Capacity Bill received Royal Assent and became the Mental Capacity Act 2005. It provides a statutory framework in England and Wales for people who may not be able to make their own decisions due to a mental health problem, a learning disability or an illness such as dementia. Sections 24 to 26 deal with advance decisions to refuse treatment. Other decisions are presumably covered by common law provisions governing consent to treatment.

3.31.2.2 Conditions surrounding the writing, validity and registering of an advance decision

A person must be over 18 and have sufficient capacity to make an advance directive. This means that a person may lack capacity in one domain (e.g. to make financial decisions), but still be considered capable of writing an advance directive. Capacity is presumed but in case of doubt, it can be established by a court of law. Although advance decisions are usually written documents, they may also be witnessed oral statements, signed printed cards or discussion notes recorded in patients' medical files. Advance decisions do not need to be witnessed by a solicitor and there is no registration procedure.

In England and Wales, people under the age of 18 can make advance decisions but they are not legally binding.

With specific reference to advance decisions containing decisions to refuse treatment, the Mental Capacity Act 2005 has the following conditions (§ 25):

- (1) An advance decision does not affect the liability which a person may incur for carrying out or continuing a treatment in relation to P (the person who made the advance decision) unless the decision is at the material time (a) valid, and (b) applicable to the treatment.
- (2) An advance decision is not valid if P -
 - (a) has withdrawn the decision at a time when he [sic] had capacity to do so,
 - (b) has, under a lasting power of attorney created after the advance decision was made, conferred authority on the donee (or, if more than one, any of them) to give or refuse consent to the treatment to which the advance decision relates, or
 - (c) has done anything else clearly inconsistent with the advance decision remaining his fixed decision.
- (3) An advance decision is not applicable to the treatment in question if at the material time P has capacity to give or refuse consent to it.
- (4) An advance decision is not applicable to the treatment in question if -
 - (a) that treatment is not the treatment specified in the advance decision,
 - (b) any circumstances specified in the advance decision are absent, or

- (c) there are reasonable grounds for believing that circumstances exist which P did not anticipate at the time of the advance decision and which would have affected his decision had he anticipated them.
- (5) An advance decision is not applicable to life-sustaining treatment unless -
- (a) the decision is verified by a statement by P to the effect that it is to apply to that treatment even if life is at risk, and
 - (b) the decision and statement comply with subsection (6).
- (6) A decision or statement complies with this subsection only if -
- (a) it is in writing,
 - (b) it is signed by P or by another person in P's presence and by P's direction,
 - (c) the signature is made or acknowledged by P in the presence of a witness, and
 - (d) the witness signs it, or acknowledges his signature, in P's presence.
- (7) The existence of any lasting power of attorney other than one of a description mentioned in subsection (2)(b) does not prevent the advance decision from being regarded as valid and applicable.

3.31.2.3 What an advance decision can cover

Advance decisions can include statements relating to:

- Treatment of medical conditions;
- Treatment of psychiatric conditions;
- Care and welfare decisions;
- Life-supporting treatment;
- Life-saving treatment;
- Appointment of a healthcare proxy and
- Research

but not the refusal of basic care (procedures essential to keep the person comfortable, e.g. warmth, shelter, pain relief and the management of distressing symptoms), the offer of food and drink by mouth or requests for euthanasia or unreasonable treatment.

3.31.2.4 Obligation to comply with instructions contained in an advance decision

To be considered legally binding, an advance decision must be clear, unambiguous and relevant. Doctors have a legal and ethical obligation to act in the best interests of patients which, in addition to clinical factors, involves taking into account the past and present wishes of patients. Advance decisions are binding only when they concern the refusal of treatment. General statements or preferences should be taken into account

and respected if appropriate but they are not legally binding. Section 4 (6) of the Mental Capacity Act states that in determining what is in a person's best interests, the person making the determination "must consider, so far as is reasonably ascertainable,

- a. the person's past and present wishes and feelings (and in particular, any relevant written statement made by him [sic] when he had the capacity)
- b. the beliefs and values that would be likely to influence his decision if he had capacity, and
- c. the other factors that he would be likely to consider were he able to do so."

In all cases, a contemporaneous decision by a competent person overrides any decision made in an advance decision. As competence is not an all-or-none affair, it should also be possible to challenge or express disagreement with a particular statement recorded in an advance decision provided that the person has sufficient capacity with regard to that decision. Doctors should comply with advance decisions even if they go against their personal beliefs or values. They may arrange for a colleague to take over a patient's treatment but if this is not possible, they must comply with a valid advance decision.

Concerning advance decisions to refuse treatment, the Mental Capacity Act (section 26, § 5) states "Nothing in an apparent advance decision stops a person – (a) providing life-sustaining treatment , or (b) doing any act he [sic] reasonably believes to be necessary to prevent a serious deterioration in P's condition, while a decision as respects any relevant issue is sought from the court."

3.31.2.5 Amending, renewing and cancelling advance decisions

An advance decision can be amended or cancelled at any time provided that a person has the capacity to do so. A withdrawal, partial withdrawal or alteration of an advance decision to refuse treatment need not be in writing (Mental Capacity Act, Section 24, §§ 4-5).

3.31.3 Access to information/diagnosis

3.31.3.1 Access to medical files

The Access to Health Records Act of 1990, which came into force in November 1991, deals with a person's right to consult his/her own medical records. A health record is understood to mean a record containing information relating to a person's physical or mental health which has been made by or on behalf of a health professional who is responsible for the care of that person.

An application for access can be made by the patient or a person who has been authorised in writing to make an application on his/her behalf. In the case of an incapacitated person, anybody who has been appointed by the court to manage his/her affairs can apply for access to the records.

Finally, there is the Data Protection Act of 1998 which stipulates that a person has the right to have access to any electronically stored information kept on him/her by another person. If the information is unintelligible to the person requesting access, the keeper of the information is obliged to explain it in a way that he/she can understand. The data controller cannot release any information if it would involve revealing information about another person who has not consented to its disclosure. The person requesting access to information must make the request in writing. Therefore, provided that a person is able to do this and understands the implications of the request, he/she should be granted the desired access.

However, there are separate provisions concerning personal data held by health professionals on the physical or mental health of a person. These are contained in the Data Protection (Subject Access Modification) (Health) Order 1987 which covers information held by or on behalf of health professionals. According to this order, access may be denied if the information is considered to be likely to cause serious harm to the physical or mental health of the data subject or if disclosure would involve revealing personal information about another person.

3.31.3.2 Independent Mental Capacity Advocates

Section 35 of the Mental Capacity Act covers the appointment of “independent mental capacity advocates” who are responsible for supporting and representing people lacking capacity who have no one else to speak for them when decisions need to be taken about serious medical treatment and long-term residential care. They have the authority to interview the person who lacks capacity in private and, at all reasonable times, to examine and take copies of the person’s health records. Independent mental capacity advocates may be required to:

- Provide support so that the person who lacks capacity can participate as fully as possible in any relevant decision;
- Obtain and evaluate relevant information;
- Ascertain what the wishes and feelings of the person who lacks capacity would be likely to be, and the beliefs and values that would be likely to influence them, if they had capacity;
- Ascertain what alternative courses of actions are available in relation to the person who lacks capacity;
- Obtain a further medical opinion where treatment is proposed and the advocate thinks that one should be obtained.

They can also challenge or provide assistance for the purpose of challenging any relevant decision.

3.31.3.3 The doctor's right to withhold information

Under the Access to Health Records Act of 1990 access to all or part of the information contained in the record may be refused if the holder of the record is of the opinion that such information is likely to cause serious harm to the physical or mental health of the patient or to any other individual.

3.31.3.4 Confidentiality/disclosure of information to other people

The Access to Medical Reports Act of 1988 deals with the disclosure of medical information about an individual to employers or insurance companies. According to this act, a person cannot apply to a medical practitioner for a medical report about someone else for employment or insurance purposes unless he/she has notified that person and received the consent of that person. If the person concerned consents, he/she may demand access to the report.

Doctors are ethically bound to respect the principle of confidentiality with regard to their patients. This is laid down in the Hippocratic Oath which states:

"Whatsoever things I see or hear concerning the life of men, in my attendance on the sick or even apart therefrom which ought not to be noised abroad, I will keep silence thereon, counting such things to be as sacred secrets."

The principle of confidentiality is also recognised in common law. However, the obligation is not absolute in that in certain circumstances a doctor may be justified in disclosing information in the public interest or as a result of having been released from the obligation by the patient. A doctor may also be obliged to reveal personal records containing information of a patient's physical or mental health under The Police and Criminal Evidence Act 1984.

There is no statute which specifically and solely deals with the issue of confidentiality. However, in a statement issued in 1995 by the General Medical Council, it is stipulated that doctors may disclose relevant information to an appropriate person or authority if the patient is mentally incapacitated, he/she would not consent to the appropriate person being involved in the consultation and the doctor considers that disclosure would be in the patient's best interests. It is further stipulated that if seeking consent to disclose information would be damaging to the patient but that disclosure would be in his/her best interests, the doctor may disclose the information without the patient's consent. This could be applicable in certain cases where disclosure of the diagnosis would be damaging to the patient but necessary for relatives to ensure the appropriate care.

Since the implementation of the Mental Capacity Act 2005, Lasting Power of Attorney for Personal Welfare and Deputies for Personal Welfare have been introduced in law. An attorney or deputy in this role could realistically expect that their authority included having access to medical and care records. Any refusal of access ought to be raised with the Court of Protection.

3.31.4 End-of-life issues and care²⁴

3.31.4.1 The principle of double effect

It is legal for doctors to administer increased doses of analgesics to a patient in order to ease his/her suffering, even if this eventually leads to the patient's death. This is known as the principle of double effect and was legalised in England following the trial of Bodkin Adams in 1957.

3.31.4.2 Euthanasia

There is no legislation which specifically deals with euthanasia or assisted suicide. Euthanasia and assisted suicide are illegal in England.

3.31.4.3 Assisted suicide

Suicide is no longer a crime in England. However, abetting, counselling or procuring the suicide or attempted suicide of another is a crime according to the Suicide Act 1961 (England and Wales). Consequently, assisted suicide is a crime and carries a jail term of up to 14 years. In September 2009, the director of public prosecutions published guidance which clarified the law on assisted suicide in England and Wales amidst uncertainty as to whether people would be prosecuted for helping someone to travel abroad to commit suicide. Attention will be paid to factors such as whether the person was deemed competent, had a clear and settled wish to make such a decision, was over 18 and did not have mental disorder but also whether the other person stood to gain financially or was acting out of compassion. No guarantees are offered against prosecution (BBC, 2009).

3.31.4.4 Murder

If a person who is of sound mind and capable of discernment illegally kills another or causes serious bodily harm leading to death within a year and a day, he/she may be found guilty of murder. The person's reasons cannot justify the action. However, according to the Homicide Act of 1957, the charge could be reduced to manslaughter if the action resulted from provocation, diminished responsibility or a suicide pact.

3.31.5 Bibliography

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3.32 United Kingdom - Scotland

3.32.1 Consent

3.32.1.1 Consent to medical treatment

Common law rules govern access to information from doctors and consent to treatment provided that a person has sufficient capacity to consent. This may still be the case for many people with dementia.

A person who is unable to make a decision relating to medical treatment due to a mental disorder (the definition of which includes dementia) is classed as incapable in Scotland. Incapacity is determined on a case-by-case basis as a patient might be able to make a decision for one form of treatment but not another. Under mental health laws in Scotland all decisions made on behalf of a person with impaired capacity must implement the following principles:

- Benefit the person.
- Restrict the person's freedom as little as possible whilst still achieving the desired benefit.
- Take account of the person's past and present wishes (providing every assistance to aid communication as appropriate to the needs of the person).
- Take account (as far as reasonable and practical) the views of relevant others.
- Encourage the person to use existing abilities and where possible develop new skills.

The Mental Health (Care and Treatment) (Scotland) Act 2003 covers only treatment for mental disorder (which might include the treatment of symptoms associated with dementia and also the treatment of concomitant mental disorders, not secondary to the dementia). The Adults with Incapacity (Scotland) Act 2000 can cover any form of treatment in circumstances where the 2003 Act does not apply if the person is unable to take the decision in question. There are special provisions under the 2000 and 2003 Acts for treatments for the reduction of sexual drive. In both Acts, the specific provisions on medication should be read along with the Principles of the Acts. The Codes of Practice give important guidance on many aspects of drug treatment.

Welfare Guardians and welfare attorneys who have medical decision-making powers can consent on the patient's behalf but not to certain medical treatments covered under the Mental Health Act or which Scottish Ministers may list. A person who has been granted an intervention order may also be authorised to make a specific decision about medical treatment on behalf of a person with incapacity.

Under section 47 of the Adults with Incapacity (Scotland) Act 2000, a medical practitioner who is primarily responsible for the medical treatment of an adult and considers him/her incapable in relation to a decision about medical treatment, is authorised to

carry out the treatment required. He/she must issue a certificate to the effect that an assessment of capacity has been carried out and the nearest relative and primary carer has been consulted (as far as practical). This certificate gives him/her the right to do what is reasonable in the circumstances, in relation to the medical treatment in question, to safeguard or promote the physical or mental health of the patient. Where the patient has several medical conditions the doctor can draw up a medical treatment plan. This will identify the necessary treatments which the person is capable and incapable of consenting to. The patient's healthcare and capacity to consent should be reviewed regularly but a certificate can authorise treatment for up to three years where the patient's capacity is unlikely to change. The certificate can also be issued by a dental practitioner, an ophthalmic optician, a registered nurse or any person described as suitable by the Scottish Ministers. These categories of practitioner are only authorised to assess capacity and treat in relation to his or her own specialism.

According to Patrick (2006), consent or refusal of treatment by a person with dementia should be respected so long as he/she has the capacity to consent to medical treatment. Once this is no longer the case, a welfare attorney or guardian may be able to consent to treatment (or refuse it) on his/her behalf (except where a refusal to treat would be life-threatening).

The Adults with Incapacity Act contains special provisions for situations where there is disagreement between the person who issued a certificate and the person/s authorised to consent on behalf of the person with incapacity. In fact it allows anyone with an interest in the patient to challenge a decision made by either the doctor or the proxy, and request a second opinion.

A new booklet 'Caring and Consent – your right to be involved in decisions about the healthcare of the adult you care for' (2009) NHS Scotland, sets out the rights of carers to be consulted about treatment plans. However, it is only legally appointed proxies with appropriate powers who have a right to make any final decisions. This booklet is available in several languages including Spanish, French, Polish and Croatian.

3.32.1.2 Consent by people who have been involuntarily detained

Part 16 of the Mental Health (Care and Treatment) (Scotland) Act 2003 deals with the issue of consent to treatment in the case of people who are subject to various compulsory measures. These compulsory measures cover people who are subject to short-term detention, compulsory treatment orders and interim compulsory treatment orders, as well as people who are subject to compulsory measures under the Criminal Procedure (Scotland) Act 1995. They do not apply in the case of emergency detention certificates (Patrick, 2006).

Certain treatments, specified by the Scottish Ministers, can only be given if the person consents or if authorisation is obtained from an independent psychiatrist. These include drug treatment after the first 2 months, drugs to reduce sex drive and artificial nutrition (but not forcible feeding). Special rules exist for electro-convulsive therapy (ECT).

If the patient has the capacity to consent to treatment but refuses to take it, ECT cannot be given even in case of emergency. This also applies to transcranial magnetic stimulation and vagus nerve stimulation (Patrick, 2006).

For neurosurgery and deep brain stimulation treatments, the consent of the patient as well as second opinions recommending the treatment are needed (even for patients who are not subject to compulsory measures). The Scottish Ministers have the authority to include further treatments to the list of those requiring second opinions.

The provisions concerning consent with or without a second opinion do not apply to any treatment:

- a. which is immediately necessary to save a patient's life; or
- b. which (not being irreversible) is immediately necessary to prevent a serious deterioration of his/her condition; or
- c. which (not being irreversible or hazardous) is immediately necessary to alleviate serious suffering by the patient; or
- d. which (not being irreversible or hazardous) is immediately necessary and represents the minimum interference necessary to prevent the patient from behaving violently or being a danger to him/herself or to others.

3.32.1.3 Consent in case of emergency

Under common law, a doctor can treat a patient in an emergency without having obtained prior consent provided he/she considers the treatment to be in the patient's best interests. This is only the case if the patient is unable to consent and provided that there was not a guardian, welfare attorney or person with the necessary authorisation under an intervention order who could have provided consent. The clinical judgement of the doctor can overrule an advance directive.

For treatments requiring special safeguards such as a second medical opinion or court approval, the Adults with Incapacity Act (Scotland) Act 2000 (s47(2)) would apply. In such cases, doctors can provide the necessary treatment to save the patient's life or to protect him/her from a serious deterioration of his/her condition. However, the Mental Welfare Commission must be notified by the doctor within 7 days of providing the treatment. If, following emergency treatment in accordance with common law provisions, further treatment is needed and the patient remains unable to consent, the doctor should then take the necessary steps under the Adults with Incapacity (Scotland) Act 2000 (Patrick, 2006).

3.32.1.4 The right to refuse treatment

A person may refuse treatment provided that he/she has the legal capacity to do so, even if he/she is likely to die without the treatment. A patient who refuses treatment may do so on irrational grounds and does not have to justify the refusal. If a doctor considers that a patient who is refusing treatment lacks legal capacity, he/she may proceed in accordance with the provisions of the Adults with Incapacity (Scotland) Act 2000 (described earlier) (Patrick, 2006).

3.32.1.5 The right to withdraw consent

In the case of people with incapacity who have been involuntarily detained and for treatment which also necessitates the patient's consent, if a patient has consented to treatment or to a treatment plan, consent can be withdrawn at any stage of the treatment (Mental Health (Care and Treatment) (Scotland) Act 2003).

3.32.1.6 Consent to non-conventional treatment

According to Patrick (2006), some complementary therapies (such as acupuncture and homeopathy) are now offered by some hospitals. Presumably, the consent procedure would be the same as for other more conventional treatments. In June 2000, the Department of Health published a booklet entitled "complementary measures; for information in primary care groups" in which they proposed key constituents of a model contract for a non-medically qualified practitioner providing services in the National Health Service:

"Patients must be fully informed about the nature of the therapy, including any side effects, and have realistic expectations of its benefits. The informed consent of the patient or, in the case of young children, of the parent or guardian, must be gained and documented."

However, many non-conventional therapies and treatments are offered privately. Some practitioners are qualified and members of recognised bodies; some are not. It is not clear what the right to consent would be in such cases.

3.32.1.7 Consent to the donation of organs and/or human tissue

The Human Tissue (Scotland) Act 2006 covers organ donation for transplantation, research, education/training or audit. Article 6 states that a person may make a written or verbal statement that his/her body parts may be removed after death and used for one or more of the aforementioned reasons. If no such statement has been made, the nearest relative of the deceased person may consent to the removal and use of a body part on his/her behalf. However, the relative is not authorized to consent to this if he/she is aware that the deceased was unwilling to donate body parts. The fact that the deceased did not consent to the removal and use of body parts is not interpreted as meaning that he/she was against it.

Article 5 states that it is an offence to remove an organ, part of an organ or tissue for the purposes of transplantation from a living child or a living adult with incapacity.

3.32.1.8 Consent to research

Section 51 of the Adults with Incapacity (Scotland) Act 2000 deals with consent to research and clinical trials.

Surgical, medical, nursing, dental or psychological research cannot be carried out on people who lack the capacity to consent to such research unless research of a similar nature could not be carried out on an adult who is able to consent to such research AND provided that the purpose of the research is to obtain knowledge of:

- the causes, diagnosis, treatment or care of the adult's incapacity; or
- the effects of any treatment or care given during his/her incapacity.

In addition, the following conditions must be fulfilled:

- The research must be likely to produce real and direct benefit to the adult.
- The adult does not indicate unwillingness to participate in the research.
- The research has been approved by the Ethics Committee.
- The research entails no foreseeable risk, or only minimal foreseeable risk to the adult.
- And consent has been obtained from any suitably authorised guardian or welfare attorney, or failing that, from the adult's nearest relative.

Research which is unlikely to produce real and direct benefits can nevertheless be carried out if it would contribute towards a significant improvement in the scientific understanding of the adult's incapacity which would be likely to lead to a direct and real benefit to the adult or to other people with the same incapacity. The above conditions would nevertheless have to be fulfilled.

3.32.1.9 Consent to clinical trials

Approval by the Ethics Committee is not necessary for the clinical trials of medicinal products provided that a favourable opinion has already been given by an ethics committee (other than the Ethics Committee) in accordance with regulation 15 of the Medicines for Human Use (Clinical Trials) Regulations 2004.

The consent of the guardian, welfare attorney or nearest relative is not needed if it was not practicable to contact such person before the decision to participate had to be taken AND consent was obtained from a person not involved in the clinical trial other than the main treating doctor or someone nominated by the relevant healthcare provider.

The consent of the guardian, welfare attorney or nearest relative is also not needed if participation in the clinical trial is considered a matter of urgency for the person with incapacity.

3.32.2 Advance directives and healthcare proxies

3.32.2.1 The legal status of advance directives in Scotland

There is no statute directly governing the use of advance directives in Scotland. The Adults with Incapacity (Scotland) Act 2000 is the main legislation on proxy decision making for adults with incapacity in Scotland but it makes no reference to advance directives. It covers financial decisions (except wills) and welfare decisions, which include all health-care, except compulsory treatment for mental disorder under the 2003 Mental Health Act. However, the Principles of the Act require the past and present wishes of the adult to be taken into account, and there must be justifiable reason for going against these.

The Mental Health (Care and Treatment) (Scotland) Act 2003 recognises advance directives in the case of people who are subject to compulsory orders (Patrick, 2006). An advance directive can be overturned by clinical judgement.

3.32.2.2 Conditions surrounding the writing, validity and registering of an advance directive

A person must be over 18 and have sufficient capacity to make an advance directive. This means that a person may lack capacity in one domain (e.g. to make financial decisions), but still be considered capable of writing an advance directive. Capacity is presumed but in case of doubt, it can be established by a court of law. Although advance directives are usually written documents, they may also be witnessed oral statements, signed printed cards or discussion notes recorded in patients' medical files.

In Scotland, to appoint a healthcare proxy (i.e. a welfare attorney), a person must be aged 16 or over and must obtain a certificate from a solicitor confirming that they understand what is involved and are not acting under undue influence.

3.32.2.3 What an advance directive can cover

Advance directives can include decisions relating to:

- Treatment of medical conditions;
- Treatment of psychiatric conditions;
- Care and welfare decisions;
- Life-supporting treatment;
- Life-saving treatment;
- Appointment of a healthcare proxy and
- Research

but not the refusal of basic care (procedures essential to keep the person comfortable, e.g. warmth, shelter, pain relief and the management of distressing symptoms), the offer of food and drink by mouth or requests for euthanasia or unreasonable treatment.

According to the Adults with Incapacity (Scotland) Act 2000, healthcare proxies (welfare attorneys or guardians) must be consulted about treatment decisions unless it is impracticable to do so (for example, it is impossible to contact the proxy).

3.32.2.4 Obligation to comply with instructions contained in an advance directive

Advance directives are not legally binding in Scotland. However, a written advance directive would have to be considered if it is clear, unambiguous and reasonably proximate. Doctors have a legal and ethical obligation to act in the best interests of patients which, in addition to clinical factors, involves taking into account the past and present wishes of patients. General statements or preferences should be taken into account and respected if appropriate but they are not legally binding.

In all cases, a contemporaneous decision by a competent person overrides any decision made in an advance directive. As competence is not an all-or-none affair, it should also be possible to challenge or express disagreement with a particular decision recorded in an advance directive provided that the person has sufficient capacity with regard to that decision.

Section 1 of the Adults with Incapacity (Scotland) Act 2000 provides five principles, which must be followed by those who intervene in the finances or welfare of an adult with incapacity under the terms of the Act. The third Principle requires that anyone intervening must take into account the “past and present wishes and feelings” of the adult as far as these are ascertainable. The final decision on what action to take rests with the person given responsibility for the intervention under the Act. This may be an attorney appointed by the adult when capable, a doctor authorised to give medical treatment, a researcher, an intervener or a guardian.

Doctors should comply with advance directives even if they go against their personal beliefs or values. They may arrange for a colleague to take over a patient’s treatment but if this is not possible, they must comply with a valid advance directive. (NOTE - This is a very grey area – the provision under Part 5 of the Adults with Incapacity Act for dealing with disputes over medical treatment would come into effect.)

3.32.2.5 Amending, renewing and cancelling advance directives

An advance directive can be amended or cancelled at any time provided that a person has the capacity to do so.

3.32.2.6 Healthcare proxies

A person may grant a power of attorney relating to his/her personal welfare in accordance with the provisions of Part 2 of the Adults with Incapacity (Scotland) Act 2000. He/she can appoint one or more persons as welfare and or financial (continuing) attorney. Personal welfare does not automatically include healthcare decisions. Powers to make healthcare decisions must be specified in the document.

For a welfare power of attorney to be valid, certain conditions must be fulfilled, such as:

- It must be made in writing by the grantor.
- It must be clearly stated the grantor wishes it to be a welfare power and to include the power to make healthcare decisions.
- It must be clearly stated that consideration has been given to how incapacity relating to the decisions covered by the welfare power should be determined. A clause can be included that sets out the specific circumstances. Otherwise it can be left to the attorney to decide when capacity has been lost.
- A certificate in the prescribed form must be obtained from a solicitor or other authorised person.

The solicitor (or other authorised person) must have interviewed the grantor immediately prior to the grantor signing the document. He/she must be satisfied, based on his/her own experience or as a result of information provided by named individuals, that the grantor understood the nature and extent of the measure. He/she must also state that he/she has no reason to believe that the grantor was acting under undue influence or that any other factor vitiates the granting of the power.

A welfare power of attorney can only be granted to an individual (not a person acting in an official capacity such as officer of a local authority, or a firm of solicitors) and does not come into force until the grantor has lost the capacity for decisions related to matters contained in the welfare power of attorney. It does not end if the grantor or the attorney goes bankrupt.

The attorney only has authority to act once the power of attorney has been registered. A welfare attorney should not be obliged to do anything which is unduly burdensome or expensive (in comparison to its value or utility) even if it is within the scope of his/her powers. Attorneys must keep records of their activities on behalf of the grantor and act in accordance with the principles.

The grantor of a welfare power of attorney may revoke it after it has been registered subject to certain conditions being fulfilled, i.e. the revocation must be in writing and incorporate a certificate in due form by a solicitor or other authorised person who certifies that he/she has interviewed the person and that the person understood the effect of the revocation and is making the decision freely.

The attorney may resign after the document conferring power has been registered. If the grantor and the attorney are married, the power of attorney would come to an end if they separate or divorce or if the marriage is annulled. In the case of civil partnerships, the same would apply in the case of separation, dissolution or nullity of the partnership.

3.32.3. Access to information/diagnosis

3.32.3.1 The right to be informed

Receiving information is necessary if people are to give informed consent and make advance care plans by drawing up a power of attorney or advance directive. However, the amount and type of information to be given is not clearly stated in a law. Provisions relating to the right to be informed are taken from case law. For example, a judge in the House of Lords stated in the context of a particular case that only fraud or misrepresentation as to the nature of treatment would invalidate consent (i.e. not inadequate information) (Patrick, 2006). On the other hand, failure to provide adequate information would represent a breach of the duty of care and could lead to a negligence claim against the doctor.

Patrick (2006) describes courts rulings which suggest a general move away from the rather paternalistic approach to providing information based on the clinical judgement of the doctor (sometimes referred to as the “reasonable doctor” test) towards one in which it is considered that information about a significant risk should be provided if it would affect the judgement of a “reasonable person”. Nevertheless, the onus is still on the doctor to assess how much and what kind of information it would be appropriate to give each patient based on the receptiveness of each patient.

It is stated in the Mental Health (Care and Treatment) Act Code of Practice (vol. 1, para. 10.02) that people under compulsory orders should be informed about the aims and effects of the treatments but at the same time, Patrick (2006) points out that doctors may nevertheless in some cases consider it unhelpful to provide such information (e.g. about possible side effects of treatment).

The Disability Rights Commission, in its guide to Good Medical Practice under the Disability Discrimination Act (1995), states that doctors should share with patients in a way they can understand the information they want and need to know about their condition, its likely progression and treatment options available to them, including associated risks and uncertainties. Doctors working in the public sector have additional responsibility under ‘The Disability Equality Duty’ (December 2006), which means that any public body needs to actively look at ways of ensuring that disabled people are treated equally.

The General Medical Council has produced a number of good practice guides which relate to circumstances where the patient is unable to give informed consent, including the issue of confidentiality.

3.32.3.2 Access to medical files

The Access to Health Records Act of 1990, which came into force in November 1991, deals with a person’s right to consult his/her own medical records. A health record is understood to mean a record containing information relating to a person’s physical or mental health which has been made by or on behalf of a health professional who is

responsible for the care of that person. However, information is not available on those records which predate the Act.

An application for access can be made by the patient or a person who has been authorised in writing to make an application on his/her behalf. In the case of an incapacitated person, anybody who has been appointed by the court with powers to access personal records, and with specific healthcare powers, can apply for access to the records. Access to all or part of the information contained in the record may be refused if the holder of the record is of the opinion that such information is likely to cause serious harm to the physical or mental health of the patient or to any other individual. A request can be made to the Court to amend the records.

The Data Protection Act of 1998 stipulates that a person has the right to have access to any electronically stored information kept on him/her by another person. If the information is unintelligible to the person requesting access, the keeper of the information is obliged to explain it in a way that he/she can understand. The data controller cannot release any information if it would involve revealing information about another person who has not consented to its disclosure. The person requesting access to information must make the request in writing. Therefore, provided that a person is able to do this and understands the implications of the request, he/she should be granted the desired access.

There are separate provisions concerning personal data held by health professionals on the physical or mental health of a person. These are contained in the Data Protection (Subject Access Modification) (Health) Order 1987 which covers information held by or on behalf of health professionals. According to this order, access may be denied if the information is considered to be likely to cause serious harm to the physical or mental health of the data subject or if disclosure would involve revealing personal information about another person.

3.32.3.3 The right to designate another person to be informed on one's behalf

Under the Mental Health (Care and Treatment) (Scotland) Act 2003 the patient has a right to designate a "named person" to receive information.

3.32.3.4 The doctor's right to withhold information

A doctor may withhold information from a patient if he/she believes that such information would be stressful or harmful to the patient's physical or mental health (Sidaway v Royal Bethlem Hospital, 1984) but he/she must have a good reason and be able to justify the decision to withhold information (Patrick, 2006).

3.32.3.5 The patient's right to refuse information

Under common law, a patient has a right to refuse information about his/her medical condition unless the lack of disclosure is deemed to be a public health risk.

3.32.3.6 Confidentiality/disclosure of information to other people

The Confidentiality of Personal Health Information: Code of Practice (1990) of the Scottish Home and Health Department states that personal information is confidential and should only be supplied to those people who are directly involved in the provision of healthcare, social care or aftercare of a patient. This has been updated in the Confidentiality Guidance published by the General Medical Council (2009) and in the NHS Scotland guidance 'Caring and Consent' (referred to earlier).

The Access to Medical Reports Act of 1988 deals with the disclosure of medical information about an individual to employers or insurance companies. According to this act, a person cannot apply to a medical practitioner for a medical report about someone else for employment or insurance purposes unless he/she has notified that person and received the consent of that person. If the person concerned consents, he/she may demand access to the report.

As a general rule, doctors and healthcare professionals must keep information about their patients confidential, even after the death of the latter. However, in the case of adult patients lacking capacity, whilst this rule still applies, there are a few exceptions. For example, a person may have been appointed who has the right to access information such as a welfare attorney or guardian. Similarly, as doctors are expected, where appropriate, to consult relatives and carers (Adults with Incapacity (Scotland) Act 2000, s 1 (4)), this implies sharing certain information about the patient with them. The doctor should nevertheless obtain the consent of the person lacking capacity to do this but if the person refuses this, the doctor should reveal the information if it is in the patient's best interests and inform him/her that he/she has done this (Patrick, 2006).

Doctors may reveal information that should normally be considered confidential if it is necessary to do so in order to prevent a serious risk to the health or safety of the person concerned or of other people, to prevent a serious crime or in the context of investigations into a serious crime (NHS Code, paragraph 7.5) (Patrick, 2006).

3.32.4. End-of-life care and issues

3.32.4.1 Palliative care

The Scottish Government (2008) has introduced a policy which recognises that people with long-term conditions, including dementia should receive specialist palliative care towards the end of life.

3.32.4.2 Special leave for carers in paid employment (to care for terminally ill person)

Carers have a right to request special care leave although granting this request is at the discretion of the employer.

3.32.4.3 Euthanasia/assisted suicide

Euthanasia and assisted suicide are considered as crimes. If someone brings about the death of another person, he/she could be prosecuted in a number of ways, e.g. for the reckless endangerment of life.

3.32.4.4 Non-assistance to a person in danger

Where a public body has been informed that a vulnerable person may be at risk of harm, that body has a duty of care to act. This measure which allows an emergency intervention was introduced in the Adult Support and Protection (Scotland) Act 2007.

3.32.4.5 Murder, poisoning and murder at the request of the victim

This is a criminal act.

3.32.5. Bibliography

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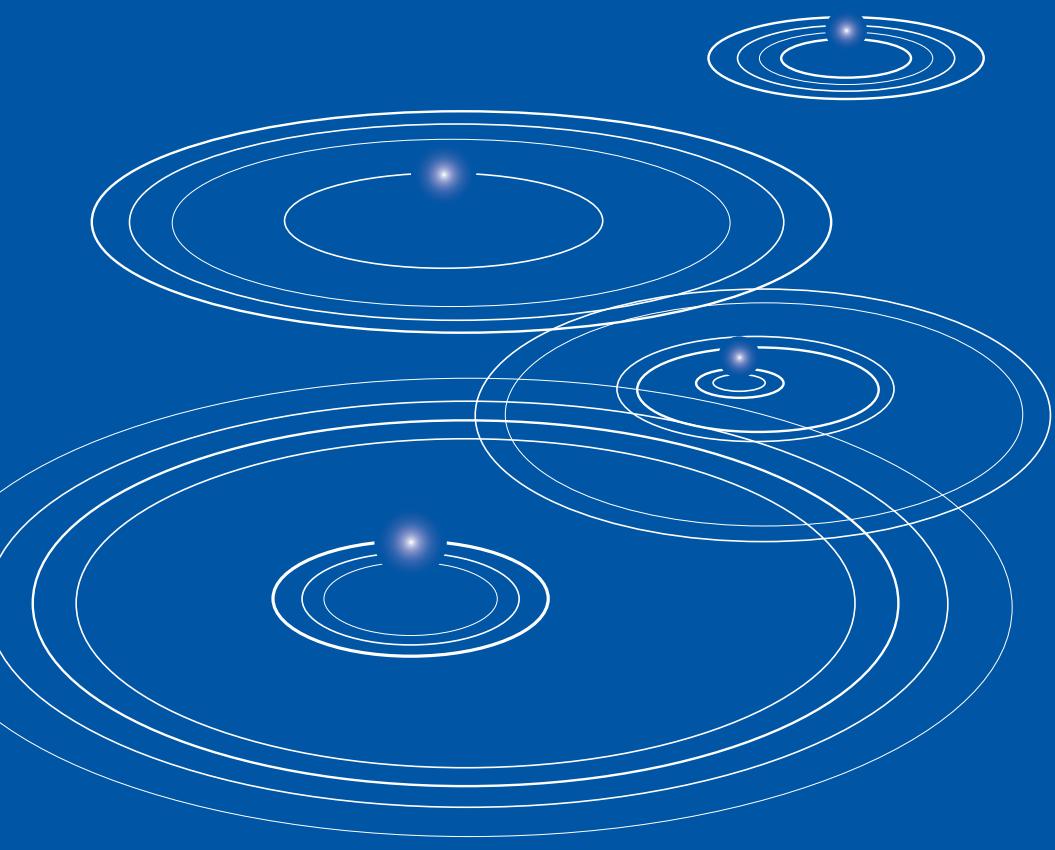
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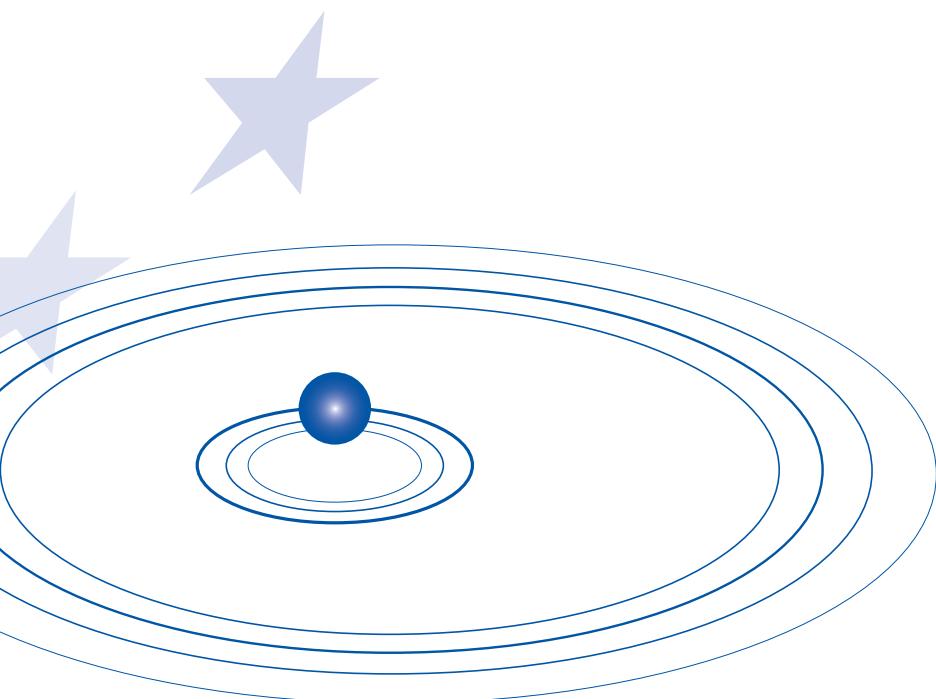






Alzheimer Europe

Annual Report 2008



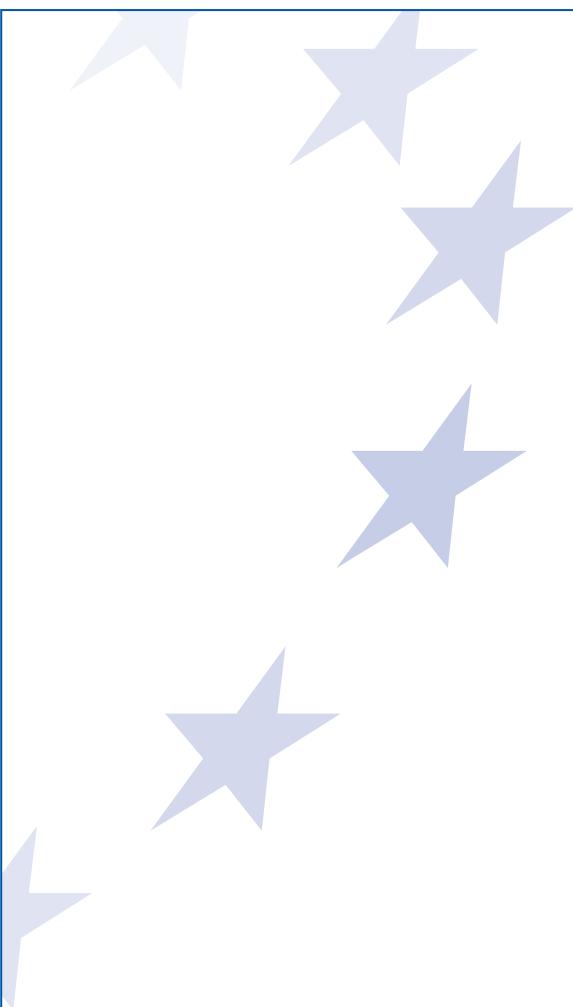
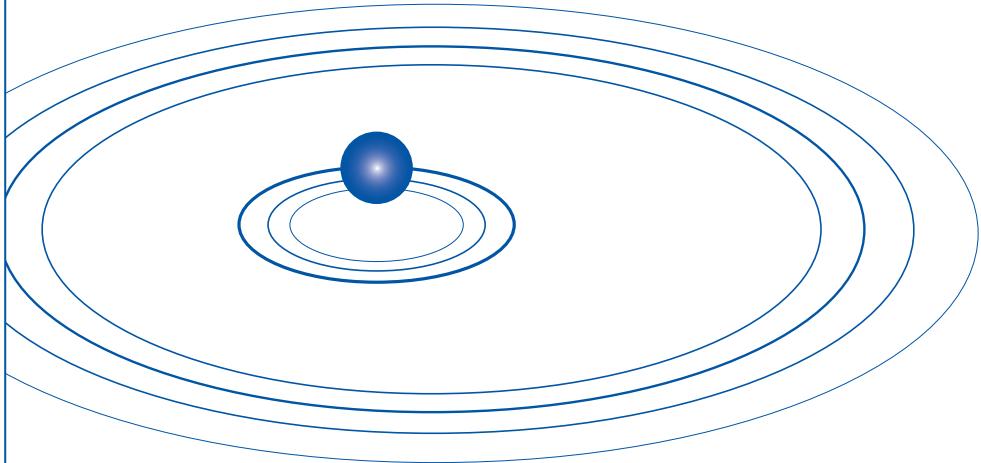


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Annual Report 2008

1.1 *Preface*



I am particularly delighted with the exposure Alzheimer's disease has received at both European and national level during 2008 and this gives me great hope that our call to make dementia a European priority seems to have been heard.

Great interest was generated in the Alzheimer Europe Annual Conference in Oslo which benefited from the attendance and participation of national European policy makers. In October, perhaps the clearest signal yet that policy makers want to address the issues which surround dementia was given during the French European Presidency Conference "The fight against Alzheimer's disease and related disorders", which saw national Ministers from around Europe and the President of France, Nicolas Sarkozy, speak of the need for a European dementia plan. That Alzheimer Europe was a part of both the steering committee for the French Conference and also of the conference presentation itself is, in my opinion, recognition of the high quality of work we carry out.

By the end of the year, the Council European Health Ministers adopted conclusions on public health strategies to combat neurodegenerative diseases associated with ageing, in particular Alzheimer's disease. Alzheimer Europe, alongside the 6.1 people with dementia who live in Europe, their carers and all stakeholders eagerly await the European Commission's response to the Council's call for the Commission to adopt an initiative in 2009 to strengthen European collaboration in the field of Alzheimer's disease.

Members of the European Parliament have also played a crucial role by pledging their support of Written Declaration 80/2008 on priorities in the fight against Alzheimer's disease. I would like to take this opportunity to give my heartfelt gratitude to the European Alzheimer Alliance members, Françoise Grossetête, (MEP, France), John Bowis (MEP, UK), Katalin Lévai (MEP, Hungary), Jan Tadeusz Masiel (MEP, Poland) and Antonios Trakatellis (MEP, Greece) for launching this initiative in October.

The Declaration is just one example of the ways in which the European Alzheimer's Alliance has strived to keep the debate about dementia alive. Alliance members also hosted the three lunch debates which were held in the European Parliament during 2008. The support by the Alliance of both Alzheimer Europe's work, as well as that of our members, has been inspiring. It was especially pleasing that Alliance members supported various World Alzheimer's Day events throughout Europe. By the year end, MEPs who had either become a member of the Alliance and/or signed the Paris Declaration stood at 88.

National dementia plans are essential if we wish to succeed in providing appropriate and effective support to people with dementia and their carers. Progress at a national level has been extremely encouraging during 2008 with the French Alzheimer Plan being implemented. I look forward to the English Dementia Strategy coming into force and hope that other governments follow suit.

Aside from assisting in initiatives mentioned above, Alzheimer Europe completed two major projects this year. The three-year European Collaboration on Dementia project (EuroCoDe), which saw 36 researchers from 20 different countries develop consensual indicators and an ongoing dialogue, had four of the six workgroups' findings published in the 2008 Dementia in Europe Yearbook. Some of the findings make for uncomfortable reading. For example, the prevalence working group found a strong likelihood that current data under-estimates prevalence rates for dementia and the socio-economic workgroup estimated the true cost of dementia in Europe to EUR 130bn. However uncomfortable these findings may be, they offer an invaluable tool in planning how we address the "tsunami" of dementia. I am extremely grateful to the European Commission for their support of the EuroCoDe project and sincerely hope we have the opportunity to collaborate again in the near future.

The Alzheimer Europe position and guidelines on "End-of-life care of people with dementia" were also published, offering a practical guide for all those involved in this delicate and demanding stage of dementia. Both projects had involved multi-disciplinary work-groups from across Europe and I am pleased that Alzheimer Europe could play a pivotal role in these projects enabling Alzheimer Europe to support their member organisations by including them in the working groups; facilitating an exchange of information; and raising the profile of both Alzheimer's disease and of our members' important work.

Alzheimer Europe began to give its communication strategy an overhaul in 2008. The first effects of this have been seen in the updated and, now, monthly newsletter as well as the launch of the Dementia in Europe magazine, of which I am particularly proud. The magazine, which is dedicated to policy on dementia, has received much positive feedback and I extend my thanks to all those who have contributed to make this possible.

These major accomplishments were achieved by a small yet dedicated and extremely capable team and I would like to thank our Executive Director, Jean Georges and his team consisting of Annette Dumas, Julie Fraser, Dianne Gove, Gwladys Guillory and Grazia Tomasini for their dedication in 2008.

Much of our work would not be possible without the continued support of the Luxembourg organisation, whose secondment of our Executive Director and provision of rent free offices have proved invaluable. The European Commission, as well as the companies (GlaxoSmithKline, Janssen-Cilag, Lilly, Lundbeck, Merck Sharp & Dohme, Novartis, Pfizer and Wyeth), which have supported us this year have also ensured that we were able to execute our extensive work programme. My heartfelt thanks go to them for their continued support.

2008 illustrated how much can be achieved when both the political will and a willingness to work together are in place. I believe that as the economic downturn takes hold, we will be presented with many challenges but I am convinced that, now, more than ever, we must persevere and continue the momentum built in 2008.

Maurice O'Connell

Chairperson

1.2 Executive summary

In 2008, Alzheimer Europe

- Actively participated in the French Presidency Conference “The fight against Alzheimer’s disease and related disorders”,
- Welcomed the adoption of Council Recommendations to increase pan-European research efforts and to launch a European Alzheimer’s initiative,
- Gathered the support of 88 Members of the European Parliament who signed the Paris Declaration or joined the European Alzheimer’s Alliance,
- Organised three lunch debates in the European Parliament in collaboration with the European Alzheimer’s Alliance,
- Saw the launch of Written Declaration 80/2008 on the priorities in the fight against Alzheimer’s disease and campaigned for the support of Members of the European Parliament in collaboration with its national member organisations,
- Launched a new “Dementia in Europe Magazine” focusing on policy developments in the field of dementia,
- Published the third “Dementia in Europe Yearbook” presenting the outcomes of the Commission financed project “European Collaboration on Dementia – EuroCoDe”,
- Gained the recognition of Health Commissioner Androulla Vassiliou as the “main network monitoring dementia cases in the EU”,
- Actively involved its national member organisations in its campaigns towards the European institutions, as well as its communication activities and projects,
- Developed its contacts with Alzheimer associations in Estonia, Hungary, Lithuania and Slovenia,
- Reviewed its communication strategy by increasing the publication of its newsletter from a quarterly to a monthly basis and by publishing the “Dementia in Europe Magazine”,
- Saw the visitors to its website increase from 670,000 in 2007 to 822,000 in 2008,
- Started work on the overhaul of its various website with a view of integrating them into a single website in 2009,
- Organised conference in collaboration with the Norwegian Alzheimer’s Association the 18th Alzheimer Europe Conference “Breaking Barriers” in Oslo which was attended by over 600 participants,
- Carried out comparative surveys on the social support of people with dementia and their carers and the legal rights of people with dementia in different European countries,

- Surveyed member organisations as to the existence of national action plans or strategies,
- Adopted and published a position on end-of-life care for people with dementia,
- Welcomed the Commission Transparency Initiative, questioned the Commission legal proposal on information to patients and supported the position on cross-border healthcare of the European Patients' Forum,
- Continued its collaboration with the European Alzheimer's Disease Consortium, the European Association of Geriatric Psychiatry, the European Federation of Neurological Societies, the Interdem network and the International Association of Gerontology-European Region's,
- Collaborated with the European Patients' Forum and worked with the European Medicines Agency,
- Finalised its three year European Commission funded project "European Collaboration on Dementia – EuroCoDe" resulting in:
 - Recommendations and examples of good practice in the provision of social support to people with dementia and their carers,
 - A report on the socio-economic impact of dementia,
 - European guidelines on psychosocial interventions,
 - A report on risk factors and prevention,
 - A review of the prevalence of dementia,
 - A European guideline on the diagnosis and treatment of dementia.
- Started the development of its Dementia Research Observatory with the aim of providing information on clinical trials to people with dementia and their carers,
- Collaborated with the German Health Ministry on the development of a European Dementia Ethics Network.

1.3 *Our strategic objectives*

1.3.1 Making dementia a European priority and representing the interests of people with dementia and their carers

During 2008, there were strong indications that our call to make dementia a European priority was being heard. This was evident by the French Presidency conference dedicated to the fight against Alzheimer's disease, by the Council of European Health Ministers adopting far-reaching conclusions aimed at helping, *inter alia*, combat Alzheimer's disease, and also by the launch of the Written Declaration 80/2008 on the priorities in the fight against Alzheimer's disease. Alzheimer Europe was included at both the planning stage of the Paris Conference as part of the steering committee and also at the conference itself, with both Maurice O'Connell (Chairperson) and Jean Georges (Executive Director) giving presentations in the plenary sessions.

The European Alzheimer's Alliance, supported by Alzheimer Europe and member organisations, worked hard to secure support from the Members of the European Parliament for the Written Declaration. Alliance members also supported national Alzheimer associations by attending their celebrations of World Alzheimer's Day in September. By the end of 2008, 88 MEPs had shown their support for Alzheimer Europe by becoming members of the Alliance and/or signing our political priorities listed in the Paris Declaration and support on at an individual level had grown to 3126 signatures by the end of the year.

Three lunch debates in the European Parliament were organised by Alzheimer Europe and hosted by Alliance members Françoise Grossetête (France), Katalin Lévai (Hungary) and Jan Tadeusz Masiel (Poland). These debates provided a platform for discussion on Alzheimer's disease and enjoyed the strong support of MEPs and their assistants.

The Dementia in Europe magazine was launched by Alzheimer Europe in June. Dedicated to policy issues surrounding dementia, the magazine had two issues during 2008 and much positive feedback was received for both issues. Alzheimer Europe's newsletter saw its circulation increase from quarterly to monthly from May onward.

The third Alzheimer Europe yearbook was published in 2008, providing the findings from the European Collaboration Project (EuroCoDe) for social support, socio-economic costs, non-pharmacological interventions and risk factors and prevention of Alzheimer's disease. In her foreword, Androulla Vassiliou, the European Commissioner for Health, spoke of the Commission's aim to give the necessary recognition required to better understand neurodegenerative diseases such as Alzheimer's disease. She acknowledged the work carried out under the EuroCoDe project and said that "Alzheimer Europe is and has been the main network monitoring dementia cases in the EU" and thanked Alzheimer Europe for "all their valuable work".

1.3.2 Involving and supporting national Alzheimer associations

Alzheimer Europe actively involved its national member organisations in its European activities with a significant number of representatives attending the various lunch debates in the European Parliament and taking part in the campaign towards Members of the European Parliament from their countries in order to secure their support of the European Alzheimer's Alliance and the Written Declaration. The involvement of MEPs in national activities provided some national organisations with greater visibility.

The Yearbook and Dementia in Europe Magazine were developed in order to provide national member organisations with comparative information on policy developments in different European countries and with much needed information to lobby their own national governments in their campaigns to make dementia a national as well as a European priority.

The activities of Alzheimer associations also feature prominently in the various e-mail newsletters which Alzheimer Europe published on a monthly basis in 2008.

Similarly, the input of national Alzheimer associations was actively sought in the development of Alzheimer Europe's position on end-of-life care.

Finally, Alzheimer Europe continued its outreach to associations not currently members of Alzheimer Europe and developed its contacts with Alzheimer associations in Estonia, Hungary, Lithuania and Slovenia.

1.3.3 Improving the information exchange between AE, its members and European structures

At the beginning of the year, the Communication Strategy of Alzheimer Europe was reviewed. The organisation changed both the layout and structure of its e-mail newsletter. Also, in order to keep the newsletter topical, the distribution was changed from quarterly to monthly).

Attention was then focused on creating a magazine, resulting in the launch of the Dementia in Europe magazine. During 2008, Alzheimer Europe has also tried to keep its members informed by using news bulletins. In particular, Alzheimer Europe kept members informed of the progress of the Written Declaration by issuing periodic updates with the breakdown by country of MEPs who had supported it.

The Alzheimer Europe website enjoyed a significant increase in visitors during 2008 up from a total of 670,098 visits in 2007 to 822,504 during 2008.

Month	Visitors 2007	Visitors 2008
January	52,697	85,050
February	45,806	62,682
March	53,640	77,837
April	45,759	79,621
May	57,415	82,058
June	66,606	67,677
July	75,573	63,658
August	67,719	58,830
September	49,676	51,210
October	50,433	72,667
November	47,373	65,884
December	57,401	54,877
Total	670,098	822,051
Average	55,841	68,504

Work began on a complete overhaul of all of our websites (Alzheimer Europe, Dementia in Europe and Alzheimer Europe Conference sites) which should be completed in 2009.

The 19th Alzheimer Europe conference, held in Oslo, saw an unprecedented 620 delegates attend over the four days. Entitled “Breaking Barriers” the conference centred around the barriers people with dementia face and how such barriers can be overcome. For many, the most memorable session was listening to Jan Henry Olsen, the Norwegian ex-Minister for Fisheries, and his wife Laila Lanes. Mr Olsen, who has been diagnosed with dementia, movingly described the impact dementia has had upon himself and his wife and talked of their desire to help eradicate the stigmatisation that surrounds this disease. Throughout the conference the message heard was that whilst barriers do exist, there is much that can be done to remove them but that this should be done in a collaborative and tailored way. Florence Lustman, the co-ordinator of the French Alzheimer plan explained the detail of the comprehensive French plan.

1.3.4 Promoting best practice through the development of comparative surveys

In line with this strategic objective, Alzheimer Europe continued the inventory of social support systems in the various countries of the European Union which provides information on the organisation and financing of social support, the services available for people with dementia and their carers and work/tax-related support provided by the State.

Also, Alzheimer Europe continued to update the reports on the legal rights of people with dementia in the different countries covered by the organisation with a view of publishing the results in the 2009 Yearbook of the organisation.

As part of the EuroCoDe project, Alzheimer Europe also took part in an overview of existing guidelines on diagnosis, treatment and psycho-social interventions which found significant differences as to the existence, status and application of such guidelines.

Finally, Alzheimer Europe carried out a brief survey of its national organisations as to the state of development of national Alzheimer's or dementia strategies or action plans which found that in 2008 only Norway and France had formal governments plans in this field and Scotland having given a firm commitment to making dementia a priority.

1.3.5 Developing policy statements

The development of a consensual approach to end-of-life care was a key achievement of Alzheimer Europe in 2008. Bringing together experts from the fields of palliative care, ethics and national Alzheimer associations, Alzheimer Europe was able to develop a thoughtful and well-balanced approach to this difficult issue and recommendations on how to improve end-of-life care for people with dementia. The work of the group was discussed at and approved by the Annual General Meeting in Oslo and resulted in the publication of a report on End-of-life care for people with dementia.

Alzheimer Europe also contributed to a number of European Commission consultations. In particular, the organisation welcomed the Commission Transparency Initiative which requires greater openness and transparency from lobbyists to the European institutions including on financial sponsorship received.

Alzheimer Europe also contributed to the Commission proposal on information to patients. Whilst welcoming the Commission drive for better information on medicines to the general public, the organisation did not support the Commission's suggestion to allow market authorisation holders to provide information on their medicines in the media such as radio, TV and print media.

Finally, Alzheimer Europe supported the European Patients' Forum in the definition of some of its more general policy statements including a contribution of the organisation on cross-border healthcare.

1.3.6 Developing strategic partnerships

As in previous years, Alzheimer Europe collaborated with other European networks active in the dementia field. In particular, thanks to its EuroCoDe project, Alzheimer Europe continued its relationship with the European Alzheimer's Disease Consortium, the European Association of Geriatric Psychiatry, the European Federation of Neurological Societies, the Interdem network and the International Association of Gerontology-European Region.

Alzheimer Europe also remained an active member of the European Patients' Forum, an umbrella organisation of pan-European patient organisations and collaborated in a number of the Forum's activities and projects.

In the framework of the European regulatory process, Jean Georges, the Executive Director of Alzheimer Europe finished his mandate as one of the two patient representatives on the Management Board of the European Medicines Agency and the organisation continued its involvement with the Working Party of Patient and Consumer Organisations. Alzheimer Europe also supported the agency in making the information on medicines in the neurological field more user friendly and understandable.

1.4 *Alzheimer Europe projects*

1.4.1 End-of-life care

As mentioned previously, the end-of-life care of people with dementia constituted a key priority project for Alzheimer Europe in 2008. Following its approval at the Annual General Meeting in Oslo, the Alzheimer Europe recommendations on end-of-life care were finalised and published.

1.4.2 European Collaboration on Dementia

The three-year European Collaboration on Dementia (EuroCoDe) project came to an end in 2008 and the findings from four (social support, socio-economic, psychosocial interventions and prevention of Alzheimer's disease) of the six working groups have been published in the 2008 Dementia in Europe yearbook. The results of the two remaining groups (prevalence and diagnosis and treatment) will be presented at the Brussels conference and published in the 2009 Alzheimer Europe Yearbook.

The project resulted in:

- Recommendations and examples of good practice in the provision of social support to people with dementia and their carers,
- A report on the socio-economic impact of dementia,
- European guidelines on psychosocial interventions,
- A report on risk factors and prevention,
- A review of the prevalence of dementia,
- A European guideline on the diagnosis and treatment of dementia.

1.4.3 Dementia Research Observatory

In 2008, Alzheimer Europe started with the inventory of clinical trials conducted in Europe in the field of Alzheimer's disease and other forms of dementia. The aim of the project will be to provide a web-based database with relevant information on all clinical trials of interest to people with dementia and their carers.

Alzheimer Europe already started providing information on the launch or results of clinical trials in its newsletter and will expand on this information by also providing more general information on the conduct of research understandable to people with dementia and their carers.

1.4.4 Dementia Ethics Network

At the initiative of the German Health Ministry, Alzheimer Europe became actively involved in plans to develop a European Dementia Ethics Network bringing together experts from different countries and different professional backgrounds in providing guidance and discussions on ethical problems faced by people with dementia, their carers and healthcare professionals. The initiative was presented at a workshop in Berlin with participants broadly welcoming the idea. Further work on this initiative will be carried out in 2009 to identify the necessary funding and partners for such an initiative.

1.5 Annex 1: Meetings attended by AE representatives

Date	Meeting	Place
9 January	European Parliament Carers' Interest Group	Brussels, Belgium
10 January	Meeting with representatives of Johnson & Johnson	Brussels, Belgium
23 January	Health grouping of NGOs affiliated to the Council of Europe	Strasbourg, France
29 January	Training seminar for patient organisations involved in EMEA activities	London, United Kingdom
29 January	Meeting with GlaxoSmithKline	London, United Kingdom
30 January	Meeting with Alzheimer's Disease International, Pfizer and Eisai	London, United Kingdom
31 January	European Commission conference "Europe's looming demographic crunch"	Brussels, Belgium
5 February	Planning Meeting for 19 th Alzheimer Europe Conference	Brussels, Belgium
6 February	Executive of the European Patients' Forum	Brussels, Belgium
7-8 February	Lundbeck Symposium	Vienna, Austria
11 February	Workshop of the European Medicines Agency on Neurodegenerative Diseases	London, United Kingdom
12 February	Planning meeting for 19 th Alzheimer Europe Conference	Brussels, Belgium
13 February	European Parliament Conference "Cancer in wide screen"	Brussels, Belgium
23 February	Alzheimer's Symposium of the Athens Alzheimer's Association	Athens, Greece
25 February	Steering Committee for the Alzheimer's Conference of the French Presidency	Paris, France
26 February	Planning meeting for the 19 th Alzheimer Europe conference	Brussels, Belgium
27 February	European life Science Circle Meeting on animal research	Brussels, Belgium
27-28 February	Patient and Consumer Working Party of the European Medicines Agency	London, United Kingdom
28 February	Preparatory meeting for the Commission conference on Mental Health	Luxembourg, Luxembourg
5-6 March	Management Board of the European Medicines Agency	London, United Kingdom
12 March	INFODAY on the Public Health Programme of the European Commission	Luxembourg, Luxembourg

12 March	Meeting with FEFAR (European Federation of Unpaid Parents and Carers at Home)	Brussels, Belgium
17 March	European Commission Conference on Elder Abuse	Brussels, Belgium
25 March	Meeting with Multimount Visual Communications	Brussels, Belgium
25 March	Meeting with Baxter Georges	Brussels, Belgium
27-29 March	5 th International Pharmacoeconomic Conference on Alzheimer's disease	Newark, USA
30 March	Alzheimer Europe Palliative Care Expert Group	Brussels, Belgium
31 March	EuroCoDe Working Group Meetings	Brussels, Belgium
1 April	Alzheimer Europe Board Meeting	Brussels, Belgium
1 April	European Parliament Lunch debate: "Is Alzheimer's disease preventable?"	Brussels, Belgium
1 April	Meeting with Eion Ryan, MEP (Ireland)	Brussels, Belgium
3 April	Meeting with Roche	Brussels, Belgium
3 April	Meeting with Parliament Magazine	Brussels, Belgium
4-5 April	Lundbeck Symposium	Budapest, Hungary
7 April	French Senate Hearing on Alzheimer's disease	Paris, France
8 April	General Assembly of the European Patients' Forum	Brussels, Belgium
8 April	Preparatory meeting for 19 th Alzheimer Europe conference	Brussels, Belgium
8-9 April	Spring conference European Patients' Forum	Brussels, Belgium
14 April	Steering committee for French Presidency Conference on Alzheimer's disease	Paris, France
15 April	Carers Intergroup in European Parliament	Brussels, Belgium
16 April	NGO Health Grouping meeting at the Council of Europe	Strasbourg, France
5 May	Meeting with German Ministry for Health	Berlin, Germany
	Institute for family policies	Brussels, Belgium
9 May	Meeting with GlaxoSmithKline	Luxembourg, Luxembourg
15 May	European Parliament celebration of the International Day for the Family	Brussels, Belgium
22 May	Alzheimer Europe Board meeting	Oslo, Norway

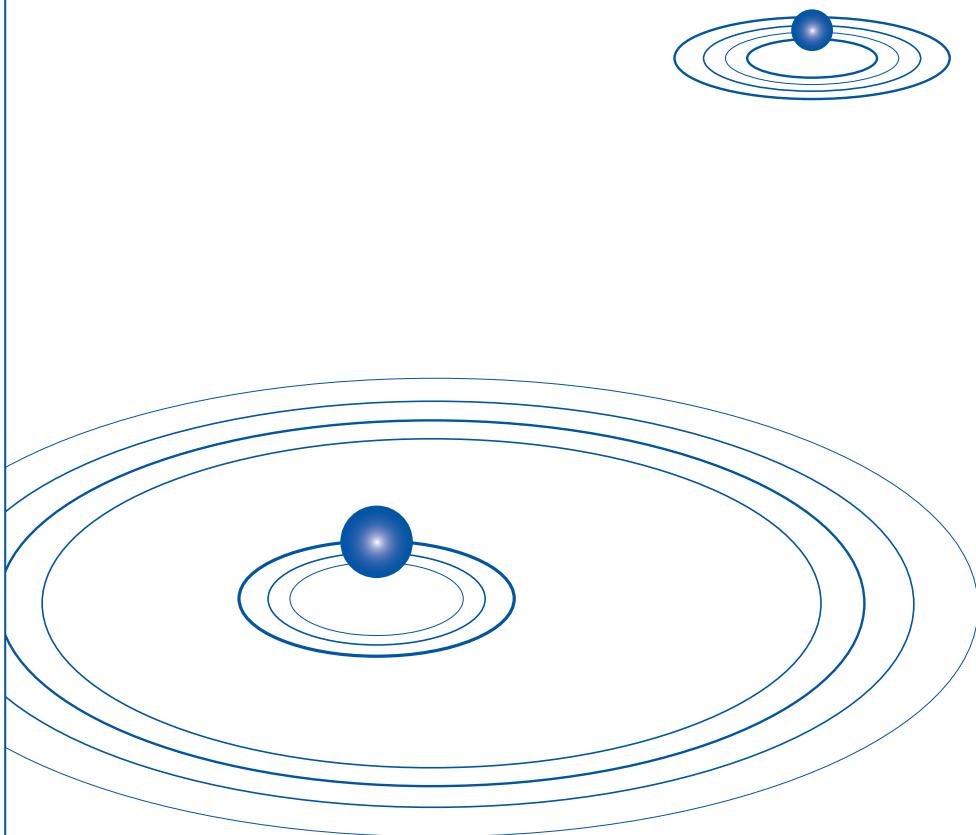
22 May	Alzheimer Europe Annual General meeting	Oslo, Norway
22-25 May	18 th Alzheimer Europe Conference "Breaking Barriers"	Oslo, Norway
25 May	Interdem meeting	Oslo, Norway
28 May	PGEU Meeting on ICT tools for the management of chronic diseases	Brussels, Belgium
28 May	EFPIA think tank	Brussels, Belgium
29 May	Weber Shandwick meeting on patient safety	Brussels, Belgium
29 May	20 th anniversary meeting of Swiss Alzheimer's association	Berne, Switzerland
5 June	Working Party with patient and consumer organisations of the European Medicines Agency	London, United Kingdom
9 June	Round-table discussion on the involvement of patients organisations	Brussels, Belgium
10 June	Meeting with Lundbeck	Luxembourg, Luxembourg
11 June	European Forum for Good Clinical practice (EFGCP) on patient safety and animal research	Brussels, Belgium
12 June	Meeting with Sirpa Pietikäinen, MEP (Finland, EPP)	Brussels, Belgium
12 June	European Parliament Carers Intergroup	Brussels, Belgium
12 June	Technical pre-meeting to the EU Mental Health Conference	Brussels, Belgium
12 June	Management Board of the European Medicines Agency	London, United Kingdom
13 June	High level conference on Mental Health organised by the European Commission	Brussels, Belgium
13 June	Meeting with Pfizer	London, United Kingdom
15 June	Meeting of the EuroCoDe work package 4 group	Berlin, Germany
20 June	The European Federation of the Pharmaceutical Industry: Partner in healthcare solutions	Paris, France
1 July	Preparatory meeting for 19 th Alzheimer Europe conference	Brussels, Belgium
7 July	Meeting with PhRMA (Pharmaceutical Research Manufacturers of America)	Brussels, Belgium
7-8 July	Seminar on media relations organised by Pfizer	Prague, Czech Republic

10 July	Meeting with representatives of the German Health Ministry	Berlin, Germany
11 July	Meeting with Elan	Dublin, Ireland
14 July	Meeting with the Pharmaceutical Group of the European Union (PGEU)	Brussels, Belgium
14 July	Meeting with Claudia Brugia from DG Research of the European Commission.	Brussels, Belgium
15 July	Environment and Health Committee meeting at the European Parliament	Brussels, Belgium
16 July	Meeting with Nicola Bedlington of the European Patients' Forum	Luxembourg, Luxembourg
26-31 July	International Conference on Alzheimer's disease (ICAD)	Chicago. USA
12 August	Meeting with Glaxo Smith Kline	Luxembourg, Luxembourg
1 September	Meeting with European Federation of Unpaid Carers at Home (FEFAF)	Brussels, Belgium
1 September	Workshop organised by the German Health ministry on the development of a European Dementia Ethics Network	Berlin, Germany
3-4 September	European Geriatric Medicine Society (EUGMS) conference	Copenhagen, Denmark
11 September	"Think tank" meeting of the European Federation of Pharmaceutical industries and associations (EFPIA)	Brussels, Belgium
15 September	Meeting of the Alzheimer Europe Board	Brussels, Belgium
16 September	Meeting with current and future sponsors of Alzheimer Europe and the Alzheimer Europe Board	Brussels, Belgium
16 September	Alzheimer Europe lunch debate in the European Parliament on the treatment of Alzheimer's disease	Brussels, Belgium
16 September	Meeting to launch the European Patients' Forum Manifesto	Brussels, Belgium
19 September	Presentation on the impact of dementia in daily life at the Danish Dementia Nurses Conference	Nyborg, Denmark
20 September	Meeting with Luxembourg Alzheimer Association	Luxembourg, Luxembourg
25 September	European Patients Forum policy meeting on cross border healthcare	Brussels, Belgium
30 September	Meeting with Binsfeld publishers	Luxembourg, Luxembourg

30 September	European conference on new approaches to home care for people with dementia	Chamalières, France
2-4 October	3rd National Alzheimer's Conference of Confederación Española de Asociaciones de Familiares de Alzheimer (CEAFA)	Vigo, Spain
8 October	Meeting with Biogen Idec	Brussels, Belgium
8 October	Meeting with PhRMA	Brussels, Belgium
8 October	Leaving party of Bernadette Bourzai, French MEP	Brussels, Belgium
10 October	Meeting with the new Chief Executive of Alzheimer Scotland, Henry Simmons and Jan Killeen	Edinburgh, United Kingdom
11 October	Meeting with Emma Reynish from the European Alzheimer's Disease Consortium	Edinburgh, United Kingdom
12 October	Meeting of the working group on prevalence from the EuroCoDe project	Edinburgh, United Kingdom
13-14 October	French Presidency Conference entitled "A Europe for patients"	Paris, France
14 October	Intergroup on Ageing on "Mainstreaming Healthy Ageing in the renewed Social Agenda!"	Brussels, Belgium
14 October	Eucomed dinner debate on "The Future of Homecare Policy in Europe."	Brussels, Belgium
15 October	Meeting with ESICM (European Society of Intensive Care Medicine)	Brussels, Belgium
16 October	FEFAD conference on "Women, Families and Society."	Brussels, Belgium
17 October	Epilepsy and Society conference	Marseilles, France
21 October	Meeting with Antoni Montserrat from the European Commission	Luxembourg, Luxembourg
23 October	Meeting with EUROPABIO	Brussels, Belgium
27 October	Seminar on the impact of dementia on grandchildren	Bradford, United Kingdom
30-31 October	French Presidency Conference on "The fight against Alzheimer's disease"	Paris, France
3 November	Meeting by Eurocarers on the "Social package"	Brussels, Belgium
7 November	Meeting with Agnieszka Szesniak (assistant to Jan Tadeusz Masiel, MEP (Poland)	Brussels, Belgium
11 November	EP lunch on "Good nutrition in Europe" organised by the European Nutrition Health Alliance	Brussels, Belgium

12 November	Health for Europe congress on the Healthcare challenges	Brussels, Belgium
21 November	EPIA Think Tank	Brussels, Belgium
24 November	Project meeting of the Pharmacog project	London, United Kingdom
8 December	Meeting of the Alzheimer Europe Board	Brussels, Belgium
9 December	European Parliament lunch debate on the socio-economic cost of Alzheimer's diseases	Brussels, Belgium
10 December	Meeting with Lundbeck	London, United Kingdom
10-11 December	EU Health Forum	Brussels, Belgium
11 December	Meeting with Pfizer	London, United Kingdom
15 December	European Commission meeting with stakeholders to discuss the Mental health thematic conference that will be organised	Brussels, Belgium
16 December	Promotion of the European Parliament Written Declaration on Alzheimer's Disease	Strasbourg, France
16 December	Meeting with representatives of Foundation Médéric Alzheimer	Luxembourg, Luxembourg





Financial Report

2.1 Report of the independent auditor



To the Board of Directors
ALZHEIMER EUROPE
 Association sans but lucratif

R.C.S. Luxembourg F2773

145, Route de Thionville
 L - 2611 Luxembourg

REPORT OF THE REVISEUR D'ENTREPRISES

We have audited the accompanying annual accounts of **ALZHEIMER EUROPE**, which comprise the balance sheet as at December 31, 2008 and the profit and loss account for the year then ended.

Board of directors' responsibility for the annual accounts

The board of directors is responsible for the preparation and fair presentation of these annual accounts in accordance with Luxembourg legal and regulatory requirements relating to the preparation of the annual accounts. This responsibility includes: designing, implementing and maintaining internal control relevant to the preparation and fair presentation of annual accounts that are free from material misstatement, whether due to fraud or error; selecting and applying appropriate accounting policies; and making accounting estimates that are reasonable in the circumstances.

Responsibility of the réviseur d'entreprises

Our responsibility is to express an opinion on these annual accounts based on our audit. We conducted our audit in accordance with International Standards on Auditing as adopted by the Institut des réviseurs d'entreprises. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance whether the annual accounts are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the annual accounts. The procedures selected depend on the judgement of the réviseur d'entreprises, including the assessment of the risks of material misstatement of the annual accounts, whether due to fraud or error. In making those risk assessments, the réviseur d'entreprises considers internal control relevant to the entity's preparation and fair presentation of the annual accounts in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control.

MAZARS - RÉVISEURS D'ENTREPRISES, EXPERTS COMPTABLES ET FISCAUX
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An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the board of directors, as well as evaluating the overall presentation of the annual accounts.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the annual accounts give a true and fair view of the financial position of **ALZHEIMER EUROPE** as of December 31, 2008, and of the results of its operations for the year then ended in accordance with Luxembourg legal and regulatory requirements relating to the preparation of the annual accounts.

Luxembourg, May 27, 2009

For MAZARS, Réviseurs d'entreprises



Joseph HOBSCHEID
Partner

Appendix:

- balance sheet as of December 31, 2008
- profit and loss account for the year ended December 31, 2008

2.2 Balance sheet as of December 31, 2008

ALZHEIMER EUROPE
Association sans but lucratif
R.C.S. Luxembourg F2773

Balance sheet as of December 31, 2008

	<u>2008</u> <u>EUR</u>	<u>2007</u> <u>EUR</u>
ASSETS		
Current assets		
Debtor EU Commission - Eurocode	174.745	59.480
Other debtors	19.680	37.314
Advance payments - Eurocode partners	10.265	27.199
Cash at bank and on deposit	<u>202.962</u>	<u>159.103</u>
	407.652	283.096
Accruals	9.590	472
Total Assets	<u>417.242</u>	<u>283.568</u>
 LIABILITIES		
Capital and reserves		
Results brought forward	106.758	90.170
Result of the year	<u>38.330</u>	<u>16.588</u>
	145.088	106.758
Creditors		
Payments received on account - Other	83.798	86.672
Trade creditors	48.235	5.752
Creditors - Eurocode partners	131.352	77.436
Other liabilities	<u>8.768</u>	<u>6.950</u>
	272.154	176.810
Total Liabilities	<u>417.242</u>	<u>283.568</u>

2.3 Profit and loss account – Year ended December 31, 2008

ALZHEIMER EUROPE
Association sans but lucratif
R.C.S. Luxembourg F2773

Profit and loss account
year ended December 31, 2008

	<u>2008</u> <u>EUR</u>	<u>2007</u> <u>EUR</u>
Other operating income		
Sponsorship	323.664	266.964
Sponsorship received on account	-83.798	-74.972
EU Subsidy	79.503	84.481
Co-financing in kind	93.832	89.409
Membership fees	48.000	47.125
Donations	485	531
Publication sales and royalties	9.873	4.253
Internet services	2.220	3.120
Project participation	21.310	16.436
Other operating income	6.479	12.598
Alzheimer Europe Conference	22.989	43.640
Unpayable debts	399	-
Eurocode Partner Income	333.146	303.036
External charges		
External experts	-160.041	-138.356
Publication and information material	-58.054	-37.309
Travel expenses	-29.663	-22.554
Communication costs	-22.010	-32.411
Accomodation expenses	-37.316	-38.109
Office rent and associated costs	-23.981	-24.962
Office stationary and related costs	-2.510	-1.976
Leasing	-12.236	-16.051
Membership fees	-1.120	-1.670
Other costs	-2.481	-2.007
Irrecoverable debt	-	-1.000
Alzheimer Europe Conference	-	-37.349
Eurocode Partner expenses	-333.146	-303.036
Staff costs		
Wages and salaries	-112.614	-97.907
Social security costs	-31.204	-27.424
Interest receivable and similar income	7.108	3.420
Interest payable and similar charges	-504	-1.332
	<u>38.330</u>	<u>16.588</u>

2.4 Annex 1: Acknowledgements

2.4.1 Support from organisations and foundations

Alzheimer Europe is grateful to Association Luxembourg Alzheimer and the Luxembourg Ministry for Family for the secondment of the Executive Director of Alzheimer Europe and the office space they make available to the organisation free of charge.

Alzheimer Europe gratefully acknowledges the generous contribution of Fondation Médéric Alzheimer to the EuroCoDe project and the support of Mazars who carried out the audit of the organisation's financial accounts free of charge.

2.4.2 Support from corporate sponsors

In 2008, Alzheimer Europe had an audited income of €949,008. Sponsorship by the pharmaceutical industry and other corporate sponsors amounted to €248,692 or 26.21%.

The following table lists sponsorship and donations received by individual companies, as well as other payments, such as speakers' fees, honoraria and support for travel and subsistence costs. The global support received from individual companies is also presented in terms of percentages of the overall income of the organisation in line with the policy of the European Medicines Agency on transparency requirements for accredited patients' organisations.

Company	Sponsorship and donations	Honoraria and travel support	TOTAL (2007)	% of AE income (2007)
Pfizer	€40,000	€486	€40,486	4.26%
Janssen-Cilag	€40,000		€40,000	4.21%
GlaxoSmithKline	€40,000		€40,000	4.21%
Novartis	€40,000		€40,000	4.21%
Lundbeck	€20,000	€9,843	€29,843	3.14%
Wyeth	€20,000	€3,269	€23,269	2.45%
Lilly	€20,000		€20,000	2.11%
Merck Sharp & Dohme	€10,000		€10,000	1.05%
EFPIA		€404	€404	0.04%
Sub-total: Support by the pharmaceutical industry			€244,002	25.71%
GE Healthcare	€3,190	€3,190	€3,190	0.34%
Innovaacom		€1,500	€1,500	0.16%
Sub-total: Support by other corporate sponsors			€4,690	0.49%
Total: Support by corporate sponsors			€248,692	26.21%

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The 2009 Dementia in Europe Yearbook presents the results of the Alzheimer Europe project on healthcare and decision-making in dementia, as well as the 2008 Annual Report of the organisation. The Yearbook provides information on the legal systems in 31 European countries with regard to consent, advance directives, access to information and diagnosis and end-of-life issues for people with dementia.

