Presidenza del Consiglio dei Ministri

COMITATO NAZIONALE
PER LA BIOETICA

DEMENTIA AND ALZHEIMER'S DISEASE: ETHICAL CONSIDERATIONS

20 June 2014

INDEX

Presentation

In the context of the debate on the social-healthcare issues of bioethics, the NBC addresses the question of dementia in this Opinion, with particular reference to Alzheimer's disease.

Starting with the definition of dementia as a state of progressive cognitive decline owing to an organic pathology leading the patient to a progressive loss of their functional autonomy, the document analyses the scientific aspects of dementia (at epidemiological, preventive, diagnostic and therapeutic level), with regard to the economic costs for society and healthcare policies at national and international level.

The Opinion examines the bioethical aspects of particular importance: personal identity and consciousness, the communication of the diagnosis (at pre-symptomatic and symptomatic level), the therapeutic relationship (with particular reference to informed consent, pain management), symptomatic treatment including the subject of nutrition (natural and artificial), social-healthcare assistance and the new technologies, information and social training.

With regard to the juridical context, the problem comes into the general area of law and mental health. In particular the juridical instruments are analysed whereby to protect forms of dementia (support administration, interdiction, incapacitation), also with reference to the legislation on compulsory health treatment. The possibility is also examined of advance directives for treatment, as an instrument that strengthens informed consent in medical choices, in anticipation of the progressive inability to understand and act, along with the question of clinical trials on persons unable to express their consent.

In the light of its scientific, bioethical and biojuridical reflection, the NBC recommends that the patient be recognised as a person in every phase of their disease; that research, prevention, therapy and healthcare assistance for the sufferers of dementia be given a significant role in healthcare policies; that studies be promoted on the modalities of communicating with the dementia patient and on the ascertainment of the level of consciousness, in order to valorise the autonomy of the patient who is still able to take decisions. The Committee considers that undue forms of disproportionate treatment or treatment abandonment must be avoided, all the more so if aimed at the reduction of healthcare costs; that appropriate access to palliative care must be guaranteed and social-healthcare assistance be integrated and flexible; that specialised training must be used for the healthcare operators, social workers and the caregivers, so as to improve the consideration of the needs of the person with dementia and the information, training and social awareness in favour of the patients and their rights.

The document was proposed by Prof. Giancarlo Umani Ronchi in the NBC's previous mandate (2013) and preliminarily drafted by the working group, with significant contributions by Prof. Adriano Bompiani.

A number of external experts were invited to give their professional advice on the subject on 20 June 2013: Prof. Gabriella Salvini Porro (Presidente Federazione Alzheimer Italia, with Dr. Mario Possenti, her assistant), Prof. Roberto Bernabei (Direttore Dipartimento Geriatria, Neuroscienze e Ortopedia del Policlinico Gemelli di Roma), Prof. Franco Cuccurullo (Presidente CNBBSV).

The subject was taken up again in the present NBC mandate by Prof. Carlo Caltagirone, who on the basis of the materials prepared, continued – together with Prof. Giancarlo Umani Ronchi – the coordination of the working group. The text was drafted on the basis of the document formulated by Prof. Carlo Caltagirone in a sitting within the NBC on scientific and bioethical profiles.

The Opinion puts together contributions by Prof. Laura Palazzani (for the bioethical part) and Prof. Lorenzo d'Avack (for the juridical part). Profs. Cinzia Caporale, Silvio Garattini, Marianna Gensabella, Demetrio Neri, Carlo Petrini, Massimo Sargiacomo and Grazia Zuffa contributed to the debate and the integration of the text.

The Opinion was voted unanimously by those present: Profs. Amato, Battaglia, Caltagirone, Canestrari, Caporale, D'Agostino, Dallapiccola, Da Re, d'Avack, De Curtis, Di Segni, Flamigni, Garattini, Gensabella, Morresi, Neri, Nicolussi, Palazzani, Sargiacomo, Scaraffia, Toraldo di Francia, Umani Ronchi, Zuffa. The members without the right to vote expressed their approval: Bernasconi, Conte, Petrini.

Profs. Carlo Casonato and Rodolfo Proietti were absent in the plenary session but endorsed the Opinion at a later date.

The President
Francesco Paolo Casavola

1. Scientific part

Dementia is a state of progressive cognitive decline owing to an organic pathology leading the patient to a progressive loss of their functional autonomy. By the term dementia reference is generally made to a chronic and irreversible neurodegenerative condition, even if totally or partially reversible dementia conditions exist (those for example due to vascular causes and/or other internal causes).

According to the DSM-IV, the Diagnostic and Statistical Manual of Mental Disorders (the 2000 revised version), dementia is characterised by the development of an evident impairment of the memory and the alteration of at least one of the following cognitive functions: language, skilled movements, capacity to recognise objects and executive functions. The seriousness of these declines must be such as to considerably impair occupational and social functioning and represent a deterioration with respect to the level of functioning prior to the onset of the condition. With regard to this subject, the DSM-V (published in 2013 and not yet available in Italian) introduces innovations of a taxonomic type, distinguishing between *major* and *moderate neurocognitive disorders*, the diagnostic criteria of which are respectively: i) evidence of a significant cognitive decline (in one or more domains such as attention, executive functions, learning and memory, language, perception or social cognition) with respect to a previous level of performance; the disorders interfere with independence in performing activities of daily living; the declines are not presented exclusively in the context of delirium and cannot be explained by a mental disorder like major depressive disorder or schizophrenia and ii) evidence of a moderate cognitive decline (in one or more domains like attention, executive functions, learning and memory, language, perception or social cognition) with respect to a previous level of performance; the disorders do not interfere with independence in activities of daily living; the disorders are not presented exclusively in the context of delirium and cannot be explained by a mental disorder like major depressive disorder or schizophrenia. In this context the dementia typical of the DSM-IV must be understood as a synonym of *major neurocognitive disorder* described in the DSM-V.

Within the global framework of neurodegenerative dementias, Alzheimer's Disease, AD, is undoubtedly the most frequent form in the elderly population (54% of all neurodegenerative dementias), followed by dementia with Lewy Body, DLB, and (Fronto-Temporal Dementia, FTD). Dementias of a vascular origin are instead called Vascular Dementias, VAD) while the dementias ascribable to other factors are defined as secondary dementias.

The prevalence of dementia, considered in all its forms, is estimated at around 6.4% of the population over the age of 65 and this doubles every five years, affecting 40% of the population over the age of 85. According to the WHO, there were about 36.5 million people with dementia in 2010 and this is expected to double roughly every 20 years: it is therefore estimated that the prevalence will reach about 65.5 million in 2030 and 115.4 million in 2050 [WHO, 2012].

In addition to the soaring and unquantifiable human costs in terms of suffering for the patients and their families, the seriousness of the economic-social impact of dementias is evident. Various studies have estimated the

overall costs that society will have to bear, according to the social cost perspective [Tarricone, 2006]. In this paper the economic 'costs' will be addressed, even though bearing in mind that the 'costs' also include the dimension of personal and social suffering at a moral level.

In the USA with reference to 2010, the annual monetary cost per dementia patient was estimated at between 41,689 and 56,290 dollars, depending on the method used to assess the indirect costs[1] [Hurd M.D et al, 2013]. Furthermore, in 2013 the *Alzheimer's Disease International* estimated the global cost of dementia healthcare at roughly 600 billion dollars, around 1% of the world GDP [Prince et al., 2013]. In the more developed countries, the informal costs component would affect over 45% of the total. On the other hand, the estimates referred overall to *brain disorders* (a very broad concept embracing some psychiatric pathologies too) in Europe (EU members as well as Iceland, Norway and Switzerland), estimated annual costs for 2010 as equal to 798 billion euros, of which over 105 billion for dementia [Olesen et al, 2012]. Of the latter over 88% represent direct non-healthcare costs (on the contrary estimates of indirect costs are not yet available). Another study based on the Eurocode project data (2008) estimated an economic impact of dementia of 160 billion euros for Europe (27 countries), including direct costs and informal care [Wimo et al, 2010]. It also appeared that in the countries of southern Europe the amount of informal costs is the largest component with respect to those of the north, in which the direct costs prevail. A recent study for France has instead calculated an average monthly total cost (direct and indirect costs) per patient equal to 2,450 and 3,102 euros, according to the method used to valorise informal care [Gervès et al, 2014].

With reference to Italy, the impact recorded at global and European level is confirmed. The last AIMA/Censis survey carried out in Italy 2006, the year in which Alzheimer patients amounted to about 520,000 according to the most recent estimates, made it possible to calculate an annual cost per patient equal to about 60,000 euros, given by the sum of the direct costs for purchases of healthcare and services and indirect costs (monetised hours of assistance and supervision) [Spadin, 2007]. The direct costs, equal to about 15,000 euros, affected the total by 25%, and were borne mostly by the family (for a figure of

[1] The analysis of the "social costs" of diseases uses three categories of costs at the most (Cavallo & Fattore, 1994; Tarricone, 2006), that is, "direct", "indirect" and "intangible" costs. The direct costs derive from the absorption of resources for healthcare (prevention, diagnosis and treatment) and non-healthcare assistance. By indirect costs is meant the quantification of the loss of production of wealth that society bears owing to the patient's condition and the time taken up by family and friends to assist them. By means of the analysis of the indirect costs is quantified the economic value of the time 'lost' by the patients and their families because of the disease and which affects the collectivity. It is important also to valorise the assistance given to the patient by the caregiver, in such a way as to consider the time taken away from work and domestic activities. The loss of productivity and the assistance provided by caregivers are valorised by means of the use of the opportunity cost method (i.e. which sets out to valorise the caregiver's time taken away from remunerated or non-remunerated work or free time, and destined to the care and/or accompaniment of the sick person) or the replacement cost method (i.e. which evaluates the time dedicated to the assistance of the sick person to the labour market price of a substitute and therefore presupposes the existence of a market substitute for each of the activities to be considered). Intangible costs refer to the costs linked to pain, anxiety, the physical and psychological suffering of the patient and their family which, even though inexpressible in monetary terms, are socially and humanly relevant. As these are very difficult to valorise they are not normally reported.

over 71%). The indirect cost component is linked to the assistance given by caregivers for almost the total amount.

In the report “Dementia: A Public Health Priority”, the WHO declares dementias as a public health priority in the coming decades. The WHO recommends: the promotion of a society at global level that is willing to take care of people with dementia; the consideration of dementia all over the world as a priority for the public health and assistance policies of each nation; the fostering of awareness on the part of both healthcare professionals and the public towards dementia; investment in healthcare and social systems to improve assistance and healthcare services for people with dementia and for those caring for such persons [World Health Organization, 2012].

In the European Union many states have adopted national programmes to tackle the problem of dementia. For example in the United Kingdom in 2012 the Department of Health adopted the programme “Living well with dementia. A National dementia strategy. Putting people first” [Department of Health, 2012]. Besides national programmes, local endeavours were also set up. For instance, in the “Mental Health Declaration for Europe. Facing the Challenges, Building Solutions”, the health ministers of the Member States of the European Region of the World Health Organisation undersigned a precise list of common commitments [World Health Organization, 2005].

Age must be considered the most important risk factor of the disease. The social-healthcare problems are particularly relevant in the countries in which the old age index (percentage ratio between population aged above 65 and population aged below 15) is high. According to the ISTAT data, there are 17 million people in Italy over the age of 60 (27% of the population). The old age index places Italy in second place in Europe (after Germany), with a ratio of 144 elderly persons for 100 young ones. According to the demographic forecasts for Italy this indicator will reach 288 elderly people for 100 young people in 2051 [ISTAT, 2014]. In Europe it is estimated that AD represents 54% of all the neurodegenerative dementias with a frequency of 5% in the overall population over the age of 65. The ageing of the population is a global phenomenon which has had a profound socio-economic and political impact during the last century and which will in all likelihood have considerable effects on the future generations too. A recent review has in fact shown how the ageing of the population will continue to grow rapidly to the point of exceeding the number of babies born over the next 30 years [Sosa-Oriz et al, 2012]. On the other hand it would seem that the dementia growth rate is destined to rise above all in the developing countries [ibidem]. In fact a recent study published in the prestigious Lancet journal shows how the prevalence of dementia has changed in the last two decades in the western world, with a clear reduction in those born later on [Matthews et al, 2013]. Furthermore, an interesting piece of work taken from the Rotterdam Study [Schrijvers et al, 2012] not only confirms the reduction of the impact of dementia from 1990 to 2005, but also shows a significant increase in the cerebral volume in the population being studied and a decrease of small vessel disease, generally the cause of vascular dementia. The survey shows how during the last twenty years factors still to be defined univocally, have affected the protection of the cerebral structure probably bringing about the deflection of the number of cases considered with respect to the number of cases expected according to the forecasts of the 90s. Moreover, it is increasingly evident that in many neurological conditions the relation between the seriousness of the cerebral tissue damage and the corresponding clinical

symptomatology is far from linear. In fact various autoptic studies have demonstrated that the brains of many elderly subjects that are cognitively integral at a clinical-neuropsychological evaluation close to death show changes that are typical of the AD pathology. On the basis of such results it is logical to hypothesize that the interaction between genetic, biological and environmental factors (such as the improvement of quality and style of life) have had some kind of effect on both the development and the resilience of the brain to the pathology.

The clinical concept of dementia (AD in particular) has undergone a considerable evolution since the proposal of the diagnostic criteria. In 1984 the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) Alzheimer's Disease and Related Disorders Association (ADRDA) [McKhann et al, 1984] formulated a number of criteria that distinguished the diagnosis of AD in a *definite* way (based on neuro-pathological results), a *probable* way (defined on a clinical basis and confirmed by neuropsychological tests, with progressive worsening deficits in two or more cognitive areas, among which memory, the starting age was between 40 and 90, and absence of disorders of consciousness and systemic pathologies) and a *possible* way (presence of isolated, progressive and serious cognitive deficits, the presence of atypical elements at the onset, in the presentation or clinical course, presence of a concomitant neurological or systemic pathology able to determine dementia). Successively, in accordance with the widely accepted idea that the onset of the pathological process proceeds the clinical manifestation of AD, the interest shifted to the possibility of carrying out an early diagnosis. In this sense the concept of *Mild Cognitive Impairment* (MCI) was introduced to define the transition phase between normal ageing and dementia, indicating therefore a population of elderly subjects without any impairment of their daily functioning, but with a sub-clinical and isolated cognitive deficit and potentially at risk of developing AD [Petersen et al, 1999, 2001]. Practically speaking the criteria adopted to define MCI are the following: presence of a subjective memory disorder, preferably confirmed by a member of the family; objectifiable memory deficit; normal general cognitive functioning; normal capacities to carry out activities of daily living; absence of dementia and other pathologies able to induce memory disorders.

More recently the criteria proposed in 1984 for the diagnosis of dementia have been re-elaborated by a group of experts [Dubois et al, 2007; 2010] with the aim of identifying pre-clinical forms of the disorder by means of the combined use of clinical and instrumental tests and biological markers. A new lexicon was introduced for this that could give valid support in the distinction between the pathogenetic process of AD and its clinical manifestation, proposing a classification that might take the early stages of the disease into consideration. In this viewpoint two different stages of the condition of dementia were distinguished: a *prodromal stage of AD* (an early and symptomatic condition preceding confirmed dementia, characterised by episodic memory loss with non-responsiveness to cueing and the presence of biomarkers in the cerebrospinal fluid or pathological changes typical of AD, identified by means of neuroimaging techniques) and an *AD dementia stage* (a condition in which the cognitive symptoms are severe enough to interfere with social functioning and the activities of daily living). This phase has three manifestations of the disease: *typical AD* (cerebral changes at the temporal-median level, of the hippocampus and the entorhinal cortex, impairment of the memory processes and another

cognitive domain, positivity to one or more biomarkers), *atypical AD* (includes non-amnestic cortical focal syndromes, such as non-fluent primary progressive aphasia, logopenic aphasia, posterior cortical atrophy, frontal variant of AD and in vivo evidence of amyloidosis in the brain or the CSF) and *mixed AD* (Alzheimer's disease together with other biological causes bringing about a cognitive decline like cerebrovascular disease). Lastly, a *preclinical stage of AD* was described consisting in a long asymptomatic period between the onset of the pathological processes of the disease and the manifestation of the first clinical symptoms.

In 2011 the National Institute on Ageing also proposed a redefinition of the diagnostic criteria for AD [McKhann et al, 2011] making a distinction between *probable AD dementia* (the symptoms start insidiously, there is a clear history of progressive cognitive impairment, the deficits are presented in an amnestic or non-amnestic form, without cerebrovascular disorders or other more serious neurological or medical pathologies that may explain the symptoms), *possible AD dementia* (atypical course with sudden onset, presence of concomitant cerebrovascular disease or other disorders that may have consequences on the cognitive abilities) and *probable or possible AD with evidence of physio-pathological processes of AD* (diagnosed respectively when: the criteria for AD are respected and the presence of biomarkers is found; the patient satisfies the criteria for a non-AD dementia but nonetheless presents the biomarkers typical of the pathological process of AD).

In this scientific and clinical debate on the new criteria to be adopted for the definition of AD, the *Società Italiana di Neurologia delle Demenze* (SINDEM) drew up a position paper in 2012 in which the choice of focussing the diagnosis on the positivity of the biomarkers is criticised [Musicco et al, 2012]. The Italian neurologists were in agreement with the identification of a preclinical diagnosis of AD and an asymptomatic stage at risk of AD, but also maintained that the evidence in favour of the use of instrumental and laboratory markers are still not sufficient to support their use in routine clinical practice.

Despite the fact that the early symptoms of dementia are quite common, it must not be forgotten that there can be many causes, just as the mechanisms involved can be. Recent studies in genomics seem to point to basic differences, which will lead to the development of specific treatment for single groups of patients, together with therapies that deal with the symptoms.

2. Ethical and juridical considerations

2.1. The problem of personal identity and consciousness

The progressive decline at structural level and the consequent functional impairment at cerebral level (together with marked behavioural changes that can also turn into aggressive behaviour) determine considerable changes in the patient's personality such as to lead family and friends to no longer recognise them, with the consequent difficulty in maintaining a bond of affection, which in some cases can be particularly serious and felt as a real sense of loss. In parallel, the patient diagnosed with dementia, especially Alzheimer's, undergoes a progressive but inexorable impairment of the memory functions, such as to bring about also manifestations of spatial and temporal disorientation (the subject may not recognise their environment despite being a very familiar place), and phenomena of misidentification (for example, exchanging members

of the family for others, even strangers). This generates serious psychological suffering in the patient from the very first stages of the disease, from anxiety for the future linked to the fear of dependence and the loss of autonomy and any decision-making ability, to existential disorientation owing to the progressive difficulty in 'recognising oneself' and 'recognising'.

The Committee does not intend to go into the philosophical debate of the various theories on the person and personal identity with reference to the dementia patient. It considers that the dementia patient must be recognised as a person in every phase of the disease, regardless of the change of the cognitive conditions, gradual or immediate that they might be, or of the change in personality and behaviour: such recognition justifies the duty to give treatment and assistance by doctors, family and society. The condition of unconsciousness or the gradual loss of consciousness and difficulty in relating with others must not be used as a justification for an ethical consideration of inferiority and a decrease in the recognition of dignity. This would introduce dangerous forms of discrimination that violate the principle of equality – the pivot of human rights – that recognises the equal dignity of every human being on the basis of existing and not of doing or on the possession of specific capacities.

The question remains as to whether this brings about a change in the sense of subjective identity of the patient, or rather of the subjective state of consciousness of psychological sensations (cognitive, affective and emotional) and perceptive sensations referred to the internal and external world. In this context various components of self-consciousness can be distinguished such as the capacity to perceive external and internal stimuli acting on the individual (*self-detection*), the ability to remember completed actions and to predict the outcome of one's conduct (*self-monitoring* and *self-agency*), the ability to perceive one's body as one's own, to recognise one's reflection in the mirror, to recognise oneself as the subject of one's own experiences (*self-recognition* and *self-ownership*) and the ability to build a coherent mental representation of oneself (*self-knowledge*). Generally speaking these meta-cognitive functions in dementias usually undergo deep changes. Unlike other conditions such as cerebral trauma or strokes, the loss of consciousness in dementias is irreversible and worsens progressively.

Such considerations necessarily entail a number of serious ethical and deontological issues. The patient needs to be made aware of their condition especially during the first stages of the disease, so that they can take decisions judiciously, also with regard to future treatment. In the intermediate stages of the disease the patient can be conscious of some aspects but not of others, and this can lead to behaviour that might jeopardise their safety (e.g. wandering), or to deeply disturbing actions for their surrounding environment (e.g. aggressiveness, delirium, apathy etc.). It therefore becomes vital to carry out an ad hoc assessment of the level and the areas in which the subject still maintains a degree of consciousness that is compatible with the ability to take decisions concerning themselves in everyday living too. This evaluation, together with a thorough examination of the degree of functionality in daily living, can give important information about the possibility of the patient functioning or participating in decision-making processes.

2.2. Diagnosis and communication

As has already been mentioned, today there is a growing tendency at international level to develop early diagnosis algorithms using innovative techniques.

The obvious immediate advantage of this approach is that it achieves ad hoc interventions that could improve the patient's quality of life and the course of the disease, as well as the possibility of planning therapy and healthcare treatment. Nonetheless this also involves risks and gives rise to important questions: is it really useful to formulate a diagnosis before the onset of the symptoms? Does this not create the risk of 'delivering' a reality to the patient that could be experienced as an inevitable sentence? Moreover, it would also have to be established who would receive the diagnosis in such early stages (only the patient or the family too, within the limits of the right to privacy as foreseen by the Italian legal system?). Without mentioning the fact that some of the instruments that make it possible to advance diagnostic hypotheses in the pre-symptomatic stages of the disease do not always give definite answers (thus leaving ample room for interpretation by the doctor) nor do they take into consideration the subjective factors of resilience. Furthermore, there is wide debate as to whether it is morally relevant to increase research in early diagnosis and, in the measure in which such research might offer concrete opportunities, and as to whether it is right and to what extent to give pre-symptomatic diagnostic access also by compulsory screening or to give it only to those people who are more susceptible to the pathology on the basis of the medical guidelines shared by the scientific community. This ethical debate is linked above all to the economic-healthcare consideration: the question arises as to how much the national health system is willing to allocate – in terms of costs – for the instrumental and biological/neurological examinations foreseen for an incurable disease, and how to balance these expenses with respect to the therapeutic-healthcare costs.

In order to resolve these complex bioethical problems, the Committee considers that the pre-symptomatic testing for dementias must not be compulsory but can be requested only voluntarily. The uncertainty of the diagnosis and the possible (even wrong) early communication of an incurable pathology would increase psychological suffering needlessly. The high cost of the tests must also be considered compared to a poor preventive efficacy (or at least the postponement of the onset of the disease). But above all the fact that, morally speaking, to subject a person to preventive measures (just as to treatment) against their will harms their dignity as a person.

As far as concerns the diagnosis of the pathology that already has a number of clinical manifestations, the doctor has the deontological and ethical duty to communicate the diagnosis in the context of the therapeutic relationship and in the respect of the autonomy and particular vulnerability of the patient. The communication of the diagnosis is particularly complex owing to the patient's cognitive and emotional difficulty in taking it in, their progressive cognitive impairment, the shock at the incurability of the pathology, the sense of 'shame' brought on with the identification of oneself with a pathology generally associated with the loss of personal dignity and social role.

The Committee considers that the patient has the 'right', but not the 'duty' to know in the context of the therapeutic relationship: this knowledge is also aimed at the possibility of interpreting the cognitive and behavioural changes that the sick person can feel from the very onset of the disease which are a

cause of anxiety and commotion. The fact that the patient is losing their cognitive ability must not be used by the doctor as a reason not to inform them directly of the pathology that they are beginning to experience. The patient seeks explanations for the changes that they can perceive: the non-communication of the diagnosis would be a mere momentary reassurance, which would furthermore interfere negatively with the possibility of treatment and assistance and lead to an increase of social stigmatisation.

A communication of the diagnosis that is given during a frank conversation in which the doctor tries to understand the 'weight' of the knowledge that the patient can bear and manages to conjugate the 'right to the truth' with the 'right to hope', according to a basic principle of ethics and medical deontology, can bring numerous benefits: the patient's understanding of their own position, the possibility to access appropriate services, the planning of their life. Even though the value of privacy must be recognised but given the necessary involvement of the members of the family in the assistance of the patient, it is important that they are informed of the diagnosis. The doctor must encourage the patient to speak about their disease with the family, even if with understandable reticence. There can be exceptions to the general rule when the patient flatly refuses to inform their family.

The modality of the communication is difficult and requires specific psychological skills, empathic capacity and a deep human sensitivity. Many authors give guidelines on the modalities and the aspects to bear in mind in the communication of the diagnosis, and there is the unanimous consensus on giving psychological support, reassuring patients and family about the resources and treatment available, and the giving of information on the course of the pathology [Turnbull et al, 2003] or on the need to make an evaluation of the individual's personality in order to prevent negative reactions, assuming an empathic approach during the conversation. These straightforward outlines, dictated by common sense, are not however always reflected in clinical practice and the attention should perhaps be focussed on the concept of the duly relativised risk factor rather than on the concept of diagnosis.

The basic principle of any clinical measure, including the communication of a diagnosis, should be without exception to act in the patient's interest.

The Committee maintains that the 'duty to know' does not exist, granting that in the case of persons who have explicitly expressed the desire to 'not know' (not feeling ready to receive the communication of the diagnosis), their will must be respected: in such contexts, the appointment of a 'trustee' or 'trusted person' that might carry out a role of intermediary between the doctor and the patient, so that the direct diagnostic non-communication does not compromise the possibility to plan the preventive, therapeutic and healthcare interventions.

2.3. Treatment

The therapeutic relationship between patient and physician

The doctor must inform the patient correctly and objectively of the course of the pathology and the real possibilities of treatment. The aim of the doctor must be, in compliance with medical deontology and ethics, the search for a continuous dialogue with the patient that is not limited to neutrally describing the stages of the course of the pathology and the options for possible treatment (and their limitations), but which also tries to accompany the patient in their acceptance of the disease and the treatment and assistance available.

The bioethical reflection has the task of urging doctors and family members to avoid the 'temptation' to abandon therapy in the dementia patient, which at times is unduly justified by means of an implicit reformulation of the category of persistent therapy, or in considering some therapies and forms of healthcare – which would be considered proportionate for patients in the same conditions with other pathologies - 'futile' and disproportionate for dementia patients, also and above all considering the costs in relation to the irreversibility of the pathology and the social stigma.

At the bioethical level it must be stressed that there is a moral duty of solidarity towards the dementia patient even with forms of serious or complete disability and a fundamental right exists to the protection of health and care[2].

Informed consent

As long as the patient is able to take decisions and there is no evidence to the contrary, the patient's autonomy, choices and orientations have priority.

As mentioned above, the diagnosis of AD does not necessarily entail the loss of the decision-making capacity. In the initial stages the patient may have lost part of their cognitive functions and for this reason not be able to manage some aspects of their life but may still possess sufficient decision-making capacity in other areas (for example, decisions regarding treatment or participation in clinical trials and research). The dementia patient's decision making capacity varies enormously according to the state of advancement of the disease. The decision making autonomy in the dementia patient must thus be considered a dynamic concept and evaluated in the various stages of the disease and in relation to the type of decision to be taken. Unfortunately standardised instruments do not yet exist that can define the competence of an individual suffering from dementia[3]. It will therefore be the task of research in neuropsychiatry to define protocols that can assess the different dimensions and the functional aspects that underlie the decision making process, so as to involve – in the measure in which it is possible – the patient in decisions regarding their own treatment and care.

In the event that the decisions have to be taken by the caregiver, they should always respect the system of values, convictions and orientations expressed by the patient during their life. It therefore seems superfluous to add that also the conditions of the patient's life (environment, care of the person), to the restrictions on personal freedom for the protection of their safety, should be implemented with the maximum respect of the patient, trying as far as it is possible to seek their approval so as not to add to the suffering. When this seems to be in conflict with the wellbeing of the family it becomes necessary to give suitable psychological support (*counselling*) with practical guidelines for close family so as to alleviate the stress caused by the disease and the daily care of the patient.

[2] Cfr. juridical part of the document.

[3] According to Grisso and Appelbaum, two American psychiatrists who developed an instrument called Competence Assessment Tool, the decision making capacity is a structured process that presupposes the ability to understand the elements of deciding (understanding), choosing (choice), judging the consequences of the decision (reasoning) and of appreciating its implication (appreciation). As far as concerns the ability to vote, for example, a number of American courts used this instrument maintaining the ability to understand and choose sufficient as a decision making standard for psychiatric patients.

Pain treatment

It must be underlined that, compared with other terminal patients, those with dementia receive less treatment for pain and have reduced access to hospices. Even though in the advanced stages dementia has the characteristics of a terminal disease (like metastatic cancer), it is not generally recognised as such, and therefore the palliative treatment that is given to cancer sufferers, cardiopaths and those with respiratory insufficiency is not given to dementia patients. The Committee considers that it is ethically important to guarantee appropriate access to palliative care for dementia patients and that research in palliation for dementia patients in particular must be increased.

Artificial nutrition

The duty to treat must nevertheless not translate into forms of therapeutic persistence. In medical practice the problem arises in particular of the duty and limits of artificial nutrition. The course of the pathology is characterised by 'sentinel events' which require a decision making process between palliative and aggressive interventions: these complications are foreseeable in the terminal stage of dementia owing above all to the difficulty in nutrition and recurring infections.

There is widespread use of enteral nutrition (EN), often not suitably justified at medical level4: the Committee recommends a thorough scientific and ethical evaluation of such choices so as to avoid disproportionate treatment, aimed at mere practical convenience due to lack of time or the reduction of healthcare costs. Non-artificial nutrition – when possible – must be considered ethically preferable, insofar as respectful of the dignity of the patient, permitting an improvement in the interaction of the healthcare personnel and the patient's family.

2.4. Taking charge of the dementia patient

Integrated socio-healthcare assistance

As dementia is a progressively degenerative and incurable pathology, assistance plays an important role, both from the healthcare and social point of view. The dementia sufferer – on the basis of the seriousness and course of the pathology, which can vary from case to case owing to the complexity of the symptoms – passes from a condition of self-sufficiency to one of dependence and serious disability requiring care and assistance and the help of others to carry out all daily activities.

One of the problems arising in the care of dementia patients is that national health assistance generally intervenes in very critical cases, when the pathology manifests itself in a full-blown acute way, given the difficulties of the healthcare system and social workers in dealing with the emerging needs owing to lack of resources and specialised training. A further problem lies in the poor interaction between healthcare services and the social services, which often results in dementia sufferers not receiving adequate support in the various stages of the pathology. Dementia sufferers are also often excluded from rehabilitation services (physiotherapy, speech therapy, psychological therapy etc.), as these

[4] As far as concerns enteral nutrition, it is justified when the products of oral nutrition are not absorbed by the intestine. In some RSAs (Nursing Homes), the placing of a PEG in patients with advanced dementia is an essential precondition as it saves time (it suffices to think of the amount of time needed for example for a patient with problems of dysphagia or bucco-facial dyspraxia.

interventions are considered as 'unaffordable' in the costs/benefits calculation (measured in relation to the recovery).

The Committee calls the attention to the need for an improvement in the quality of integrated socio-healthcare assistance for the dementia sufferer and for the adequate specialised training of healthcare personnel and social workers. The improvement in assistance is the condition for the improvement of the quality of life of the dementia patient and their family. Rehabilitation services must also be made available for those with dementia just as they are for any other patient, on the basis of the clinical need to improve their psycho-physical conditions.

At international level a proposal has been made for the figure of the '*dementia care-adviser*' (or even '*disability manager*') trained specifically to advise and help the patients and families to access the appropriate services, at the level of physical and psychic, cognitive and emotional assistance. These services must be flexible and commensurate with the actual specific needs of the single patient and their family.

Next to the figure of the '*care adviser*' there is the role of the *'caregiver'* or '*carer*', often carried out by members of the family or by '*in-home hired carers*' (it would be better to use the expression '*family assistants*'), a job that becomes increasingly heavy as the pathology progresses. This is a complex role owing to the physical and mental 'exhaustion' of the care and one that is often underestimated and ignored. Appropriate information/training is needed to guarantee the maximum competence and quality of services and appropriate support for the '*caregiver*' from the initial stages of the disease to the terminal ones, as the patient's quality of life also depends on the humanisation of the assistance. A valorisation of the professional figure of the 'family assistant' is to be fostered, hopefully contributing to the creation of a family and social network around the patient, stimulating significant reactions.

The bioethical criteria for taking charge of the dementia patient

It is not easy to draw up general ethical guidelines that might constitute a point of reference for the decisions and healthcare interventions for the dementia patient, as the signs of the pathology can be extremely variable in the different sufferers and in the various stages of the disease.

The Committee considers that assistance for the dementia sufferer must aim at the valorisation of autonomy (within possible limits), balancing this with safety (towards the patient, the family and society).

When reference is made to autonomy, it is always meant in a relational context, whether one thinks of the rational capacity and self-determination in choices which are progressively dimmed in a dementia sufferer, or if one looks at their possibility of self-expression by desires, feeling and emotions. The condition of wellbeing of the dementia sufferer is linked not only to the improvement of their cognitive ability but also to the realisation of positive relational experiences which must be evaluated in daily living as they are constantly changing (at an emotional and behavioural level).

In this perspective the patient's conscious choices must be balanced according to the needs for protection and safety, understood as the minimisation of risk, with reference to the sick person, their family and society. The balancing must weigh up the possible risk and potential benefit, considered in relation to the real specific condition of the patient's wellbeing. The balancing must not have the convenience of others or of society as parameter, to the detriment of

the sick person (limitation of their autonomy, decline of wellbeing). An example of this is the excessive use of sedatives, administered with the specific purpose of improving the wellbeing of the family or of whoever is taking care of the person and rarely in the patient's interest.

The use of new technologies for assistance

New technologies are being designed for the assistance of dementia sufferers. 'Smart homes' (intelligent instruments that allow the house-ridden dementia sufferer to increase their mental and functional autonomy), 'telecare' (the use of remote technologies to monitor their health, facilitating communication of the sick person with the healthcare facility); 'monitoring' and 'track devices' (technologies that give the position of the patient); 'memory aids' (audio or visual technologies that aid with messages to remember, stimulating interaction and improving memory).

These instruments are undoubtedly very useful in improving the efficiency, autonomy and quality of life of the sick persons, their families and carers. The research, realisation and diffusion of these instruments must be encouraged and economically and ethically backed.

It must nonetheless be stressed that the use of such technologies, if not appropriate and proportionate, can lead to an impoverishment of human relations in the measure in which they substitute and do not integrate the 'responsibility' for dementia sufferers; in such cases it can lead to a reduction of freedom and privacy. In this sense it is important that the fully informed and conscious patient expresses him/herself with respect to their acceptance or refusal of such technologies, in the balancing of the risks and benefits given by them (also in the DAT context). It is moreover important that during the technological design phase, such instruments foresee modalities that respect the patient's privacy (*privacy-by-design*).

2.5. Information and social training

At the ethical level appropriate social information on the pathology is of particular importance (how it is manifested, the incidence, the consequences for the person and society, treatment and assistance). Information is also important in a preventive function. The most recent research has highlighted how a good lifestyle (nutrition, physical exercise, no smoking or alcohol abuse) and, above all good intellectual exercise can prevent the pathology, maintaining cognitive ability and functional autonomy, delaying the onset of the pathology and reducing its worsening.

Social awareness must be accompanied by social training. Professional training in the individual and collective responsibility with regard to this pathology: individual responsibility insofar as the degree of personal commitment to health preservation – suitable lifestyles – and to cognitive exercise permits an accumulation of 'cerebral and mental reserves' that protect the individual from the onset of the disease (or at least can slow down its worsening); social responsibility, in so much that individual commitment must be constantly sustained also by the contribution of those close to them (family, friends, society in its entirety) to cognitive and relational stimulus, avoiding forms of abandonment, stigmatisation and isolation that increase both the onset and seriousness of the manifestation of the pathology.

Information and training must aim at fighting the social stigma of dementias, promoting Health Ministry information and social awareness

campaigns for the right/duty to social inclusion and the importance of solidarity. These campaigns must also inform citizens of the right to non-discrimination and stigmatisation, publicising the rights of the disabled, with specific reference to dementias.

The objective must be that of the 'normalisation' of dementia, or to bring it back within the common human condition like other serious disabilities, fostering campaigns for devising 'good practices' of social inclusion.

The standard education of doctors and socio-healthcare personnel, *care-givers* and volunteers must be extended to include not only scientific training but also ethical and human training in care and assistance.

2.6. The law and mental health

Safeguarding the dementia sufferer in the context of mental health protection

Like any other human being, the person with Alzheimer's disease – in every stage of the disease and at every age considered – has the right to the protection of their dignity, to their rights as a person and to protection and healthcare, according to the constitution and laws of Italy (arts. 2, 3, 13, 32 Const.). These needs can be translated into the enhancing of the rights of the patients and their families, in fighting prejudice and discrimination and in adopting appropriate policies and legislative instruments.

This strategy for the respect of human rights is a programme that international and European documents on mental health have in common, comprising the WHO and the UN, the EU and the Council of Europe[5]. There are many charters that recommend that national legislations guarantee the rights of the person with a mental disorder, including their right to appropriate healthcare. A number of rules have been drawn up with the invitation to become the subject for drafting in national legislations. These rules focus on various aspects.

Society must be aware of the reality of mental health, since a population that is also in poor mental conditions represents a heavy burden for the institutions financing public health. The new issues regarding mental health are for the most part linked to the structure of modern societies. Even if mental health concerns the general equilibrium of a society, it occupies a modest place in the overall concerns of the state authorities. In numerous cases for example, depression is not always considered and approached with due attention and therefore only a small minority of people at present hit by it can benefit from satisfactory patient care.

Even if the recommendations translated into rules aimed at affirming the rights of the persons with dementia have obliged various states to review their legislation in order to conform with them, it must be remembered that the introduction of these rules into the national legislations cannot be sufficient if not accompanied by a renewed will with regard to the responsibility for mental healthcare. In order to elaborate such policy it is fundamental that the viewpoint

[5] Council of Europe: Recommandation No. 1715 (2005) Pour une meilleur réponse aux besoins de santé mentale en Europe; Résolution 1460 (2005) relative à une meilleure réponse aux besoins au matière de santé mentale en Europe; Recommandation Rec 10 (2004) relative à la protection des droits de l'homme et de la dignité des persone atteintes de troubles mentaux; Recommandation 4 (1999) sur les principes concernant la protection juridique des majeurs incapables: European Parliament: European pact for mental health and well-being (2008). International charters: Helsinki Declaration on metal health in Europe, adopted during the conference of ministers organised by the WHO in January 2005 in Helsinki; 2001 WHO report on mental health: Mental health: new understanding new hope.

of the sufferers and their families be taken into consideration as well as that of the professionals. It is moreover essential to give support and help to the families of those with dementia given that, as experience shows, either voluntary or involuntary treatment is effective only if there is strong support from the community in the subject's living environment.

Further concern is given by the institutional organisation for the taking charge of mental disorder which must be carried out by specialised services, so as to deliver adequate treatment, corresponding to specific therapeutic needs. It must be highlighted that in a number of countries including European ones, the lack and inadequacy of assistance for people with mental disorder leads to situations that are inhuman and degrading.

The organisation taking charge of mental healthcare must be increasingly integrated with the notion of networking, associating public psychiatry with general medicine and other branches of medicine, the overall facilities of private health, medico-social institutions and the numerous partners belonging to NGOs. Whatever the cultural and administrative organisation may be, the rules and responsibility for mental health must be part of the general facilities of the national health systems.

It is recommended that the problem of hospitalisation and involuntary treatment be dealt with very carefully by the national legal systems, as they represent situations in which the rights of man and his dignity can be more greatly exposed to being violated. It is of primary importance that each state declares which authority is entrusted with ruling on hospitalisation or mandatory treatment and that this offers the maximum guarantee with regard to its independence and that any possible contestations to its decisions be made within the framework of procedures guaranteeing as much the rights of the persons involved as the serenity needed for a decision relative to this type of hospitalisation. The trend in legislations to let the judge intervene in these decisions is to be hoped for in the future.

Hospitalisation and involuntary treatment must nonetheless be considered as exceptional cases and justified by specific reasons. Thanks fundamentally to the professional training of the group of operators involved in these cases, psychiatric treatment must in practice be based on an individualised approach that entails the elaboration of a treatment protocol for each patient.

The need is once again stressed that the rights to information, communication and visits are guaranteed and that rules are applied in order to ensure the protection of the patient facing specific situations (isolation and containment) and treatment that can be particularly invasive.

Juridical instruments for the protection of the dementia patient

Most of these recommendations have by and large been contemplated by the Italian legislator.

The juridical instruments to protect forms of dementia, which can make the subject progressively unable to understand and act, thus guaranteeing the patrimonial and existential rights and interests of the mentally incompetent, are given by the "support administration" (art. 404 and seq. c.c.)[6], by "interdiction" and "incapacitation" (art. 414 and seq. c.c.).

[6] It is important to remember that also a member of the family indicated by the patient or an trusted external person can be appointed as support administrator, subject to a careful evaluation by the supervising judge.

The legislation does not set down clear selective criteria to distinguish the use of one or another institute and this therefore gives rise to three 'partially functionable' legal points, in fact leaving the choice of which instrument is really applicable with the judge's decision, which on the one hand guarantees the incompetent the most suitable protection to the case in point and on the other limits their capacity in the least measure possible and allows the powers representing them to be specifically correlated to the features of the actual case.

From a jurisprudential point of view the institute that is principally used is undoubtedly the support administration. Only in the case that interventions are not recognised in this context that are suitable to ensure the incompetent person sufficient protection, will the judge resort to more invasive measures of incapacitation or interdiction, which attribute a *status* of inability, extended to acts of extraordinary administration for the incapacitated person and for the interdicted to those of ordinary administration too.

There is no doubt that with the support administration the legislator set out to create an elastic instrument, tailored to the needs of the concrete case, which can be distinguished from interdiction not so much under a quantitative profile as under a functional one. It must not be excluded that generally speaking in the presence of particularly serious pathologies recourse can be made to either one or the other protection instruments and that, as said above, only the specific features of the single cases and needs, to be defined each time, can determine the choice among the various institutes. In fact, interdiction has nevertheless a residual character, as the legislator set out to reserve it on the basis of the seriousness of the effects deriving from it to the hypothesis in which no protective efficacy would bring about a different constraint (Const. Court, No. 440/2005; Cass. civ., No. 12466/2007 and Cass. civ., No. 9628/2009). Above all, should interdiction be requested, mental infirmity must be ongoing and habitual, that is, steady and sufficiently prolonged. The concept of *habitualness* must not be confused with *continuity*: the existence of lucid moments that may be more or less lasting does not represent an obstacle to the declaration of interdiction or the support administration.

The family – in all the above mentioned circumstances – shall not be 'excluded' from the judge's decisions; there is no doubt however that, with respect to what happened in many cases in the past, there is a greater tendency to evaluate the residual faculties of the dementia patient as far as possible in terms of decision-making through 'dialogue' and a better understanding of their interests.

Compulsory treatment in the Italian legislation

As extensively highlighted in the Charters and recommendations here above, the situations that can mainly question patients' rights are those of placement or compulsory treatment.

Act No. 833 of 23 December 1978, (Institution of the National Health Service) in art. 34 and seq. foresees voluntary and compulsory examinations and treatment for mental disorders, the latter generally referred to as CTOs (Community Treatment Orders).

Apart from a number of very rare exceptions, in practice this treatment is regulated only in the psychiatric context by means of the compulsory admission to psychiatric wards in public hospitals.

It is important to remember how the legislation in question reaffirms the constitutional rule of the voluntary nature of treatment, giving the cases of

compulsoriness as exceptions. There follows the respect for the dignity of the person and the patient's civil and political rights, as set down in arts. 2, 3, 13 and 32 Const., and, within all possible limits, their right to the choice of doctor and place of treatment.

The conciliation of forced treatment with constitutional principles has led to many hermeneutical debates which the NBC does not intend to go into here. It just observes that in the context of the CTO the legislator, through the intervention of the judge[7] and case by case evaluation, set out to guarantee the rights of the single patient, the protection of their health while at the same time respecting the conservation and development of their personality.

It is important to consider that the elements connoting the law are: - the presence of an authority charged with the decision to section a patient - the person needs treatment according to the examining physicians; - the patient refuses the treatment and is dangerous for him/herself and for others; - it is not possible to use other less restrictive criteria and temporary and transitory hospital admission is nevertheless therapeutic; - compulsory treatment shall respect congruity, symptoms and proportionality to the person's state of health; - the treatment shall be part of a written treatment plan, handed to the person concerned or to their legal representative and, as far possible, discussed and coordinated with them (given also the possibility to choose among a series of alternative proposals) and if necessary modified in time; - the judicial authority, the judge supervising the guardianship, shall be informed and affirm the provision within a tight deadline; - should it be necessary, the judge shall adopt urgent measures that may be necessary to maintain and administer the patient's patrimony; - whoever is subject to CTOs and whoever is interested in doing so can appeal to the competent regional court against the measure validated by the supervising judge.

A common grievance by scholars is that the Italian legislator was confined to stressing the possibility that certain treatments are compulsory, without indicating which ones and in actual fact in which hypotheses. This entails evaluations of marked technical discretion, such as to in fact reduce the supervising judge's validation function to the purely formal dimension of an external control of documents. A charge of generalness and indeterminacy in the definitions of the premises of the CTO, particularly in relation to the profile of the respect of the principle that compulsory treatment shall be imposed only by the law.

This standpoint, geared towards the defence of civil liberties, is not reflected in other parts of the legal framework and constitutional jurisprudence that states that, if accompanied by suitable guarantees, coercive measures can be foreseen by the law and that sectioning is not in contrast with art. 32, par. 2 Const.[8]. The CTOs can have the objective of having to attune to the basic interests of the community, which can require the subordination of the person to compulsory treatment, implemented also in the patient's interests or of foreseeing their subjection to particular obligations.

[7] According to the Italian legislation the CTO is set down by a provision of the mayor in his position as healthcare authority and representative of the municipality where the person resides. The CTO ordinance needs two medical certificates stating that: - the person is in a situation of change such as to require urgent treatment; - the proposed interventions have been refused; - it is not possible to adopt timely measures in facilities other than hospitals. All three conditions must be present at the same time and certified by two NHS doctors.

[8] Const. 39/1977; 399/1996; 218/1994.

In the Italian legislation it must be recognised that, following the national and international guidelines here above, as well as being legitimated jurisdictionally the whole procedure is surrounded by extrajudicial guarantees of a socio-healthcare type, aimed at the respect of the person and at making the medical profession and local administrators responsible for the decisions involving the lives of others. The punitive use of containment or any physical or mental violence on the part of the operators are offences punishable by the law.

In terms of the 'rights of the person', it must be added that the Italian legislation focuses the attention on sectioning for therapeutic reasons and therefore aimed at the 'treatment of mental disorder' and not in relation to the limitation of freedom, independently of the need for treatment. A patient can be sectioned in a mental institution involuntarily only if they represent a significant risk of serious harm to his or her health or to other persons as a result of their mental disorder. It must be said that the Italian legislation is in line with the *Recommendation on the protection of the human rights and dignity of persons with mental disorder* issued by the Council of Europe in 2004. The Recommendation stresses the principle that a person with a serious mental disability can be subject – without their consent – to an intervention aimed at treating their disorder only if it is likely that without this treatment they could be a significant risk of serious harm to their health and with the reservation of the conditions of protection provided for by law, including the supervision and control procedures, as well as appealing legally.

The flexible balance between health, rights and dignity is guaranteed also considering the rise in human rights protection and the need for the recovery and reintegration of people suffering from dementia, in conditions of fragility, loss of vitality and weakened by social barriers.

Nevertheless in the context of the law and the regulation of healthcare interventions with regard to these categories of patients, one should think of a *soft*, peculiar right, which needs to be based on scientific, clinical and physiological data that is continuously evolving. A 'right in movement' therefore, steeped in deliberately general concepts and provisions, where the norms are not able to define with sufficient precision what the law prescribes, authorises or forbids. Therefore most of the decision concerning what to do before a situation perceived as full of risks for the rights of the patients above all lies with the group of operators who, on the basis of the professional cultures in force in the single institutions, personal experiences, at practical and training level, must see to the treatment of the patient in that specific situation. They are the people who should, as the NBC stated, 'have a clear vision and understanding of the possible choices of treatment, starting with the less restrictive ones, to be used when the patient at a loss becomes confused, irritable, frightened and can lose control. Each and every patient must be offered the chance to express themselves and the staff must take the time to stop, observe, listen' (*Psychiatry and mental health: bioethical guidelines*, 2000, 47).

Advance directives for mental health treatment

In these cases the possibility is recommended for the patient to avail of the so-called *advance directives for mental health treatment* (ACD)[9], to be used

[9] This denomination refers 'to a document whereby a person, in the full possession of their mental faculties, expresses their will concerning the treatment they desire or do not desire to undergo in the case in which, during the course of a disease or owing to sudden serious

when they can no longer choose for themselves. In these cases the ACDs represent an instrument that strengthens informed consent in medical choices, giving a further possibility of involvement to the doctor's professional duties and to the legitimation of medical action, moreover giving substance to the patient's right to personal integrity.

In reality analogous *advance directives* can also be useful in giving guidelines with regard to the wishes of the person that, in view of the their progressive inability to understand and act, is concerned about the many aspects of their future life. In this sense they are also a further instrument of the person's autonomy and can influence choices other than medical ones, that will be taken in the interest of the mentally incompetent, identifying and reconstructing their will that can longer be expressed. This is all the more true when one sees that the recurring terms used in this subject (power of attorney, curator, trustee) evoke old private law figures first of all linked to the will and availability of the subject's patrimonial interests. In the context of protection these figures combine the interests of the person being administered: personal with property interests.

In the case of mentally incompetent subjects the decisions taken must always and anyway be taken in their best interests, so that having knowledge of the will of the latter concerning their personal choices on treatment and patrimonial provisions can only be of help in the decision made by the third party, whether it be the doctor, a member of the family or the legal representative or judge.

It will be the responsibility of each of the parties charged with managing the life of the mentally incompetent to attribute greater or lesser attention to these *directives* in consideration of the urgency and circumstances of the situation. The responsibility for the decision making still lies with the doctor or legal representative in the different cases, along with the importance of their evaluation in the light of the *directives*. Nevertheless the principle must remain firm that if these figures, to their best of knowledge and belief, are convinced that the patient's wishes are still relevant, to respect them cannot be configured as a diminution of a decision making responsibility, but only as the fulfilment of the respect of the patient's freedom and dignity. Undoubtedly the directives could not and should not be disregarded a priori, as if they had never been drafted.

In addition, at the moment in which the subject expresses his or her own will in writing they must be conscious that all the advance directives have an inevitably precarious, contingent and uncertain nature. Nevertheless, outwardly their firm will to put the directives in writing has the meaning of wanting to personally and fully assume such risk at a moral and juridical level. With regard to this the NBC stated: 'As it is a question of an adult, an autonomous and informed subject, in the full possession of their mental faculties, as well as being personally convinced of the opportunity to make advance directives, there is no reason why the risk that they would consciously decide to run should work in the sense of taking away the validity of their express desires'[10].

It must also be added that the principle according to which the person maintains the right to revoke or change their will makes it possible to give these

injuries, they were not able to express their informed consent or dissent'. Definition given in the NBC's document, Advance treatment directives, 18 December 2003.

[10] NBC, Declarations, cit.

written directives a more definite value. In the case of the person with dementia it often happens that the disease has moments of lucidness or partial lucidness and should the patient express the desire to revoke or change the *directive* this will must be respected, also in the doubt that they may not be fully conscious, bearing in mind the patient's specific conditions.

The NBC expresses its hope therefore that, from an ethical and juridical point of view, the advance directives, supported by a power conferred to the trustee or the legal representative[11], might survive the loss of the subject's mental faculties.

2.7. Clinical trials with dementia patients[12]

Legislative decree 211/2003, article 5 (entitled 'Clinical trials on adults not able to validly give their informed consent') sets down that: '(…) the participation in clinical trials of mentally incompetent adults who have not given or who have not refused their informed consent before the disablement appeared is possible only in the case that (...) the informed consent of the legal representative has been obtained(…)"[13].

This provision is in compliance with the most important documents on the ethics of research on man, whereby it is laid down that the consent for experimentation, in the case of so-called 'incompetent' persons, shall be expressed through a legal representative (see for example, art. 28 of the 'Declaration of Helsinki'[14] and art. 15.1.iv of the 'Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research'[15]), even though exceptions to such provisions are foreseen (see art. 15.2 of the same protocol). Nonetheless it must be considered that in other nations the figure of the legal representative also has different forms with respect to the one foreseen by Italian law. As mentioned above, in Italy the institutes of interdiction and incapacitation are now opportunely in disuse. Moreover also the number of adults incapable of expressing their consent and for which reason a support administrator is appointed is tiny. Consequently in accordance with the law, it is almost impossible to carry out clinical trials on incapacitated adults not capable of personally expressing their consent.

Very often, especially in neurological cases, the experimenters make use of the consent expressed by a member of the family or a caregiver, even if this is not legally valid. From an ethical point of view, it is right to consider the consent expressed by persons close to the patient. This moreover corresponds to the approach foreseen in the Civil Code (art. 408) for the choice of the support administrator by the supervising judge (where it sets down that: 'In the

[11] The obvious aim is that there must always be a subject capable of interacting with the doctor or judge, in such a way that the impossibility of expression of the subject incapable of self-determination causes limited harm.

[12] Cfr. the Opinion Clinical trials in adult or minor patients who are unable to give informed consent in emergency situations (2012).

[13] Legislative Decree No. 211 of 24 June 2003. Implementation of directive 2001/20/EC relative to the application of good clinical practice in the carrying out of clinical trials of drugs for clinical use. Official Gazette of the Italian Republic – General Series 9 August 2003, No. 184, ordinary supplement No. 130, 9 August 2003.

[14] World Medical Association. Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects. (amended by 64th WMA General Assembly, Fortaleza, Brazil, October 2013). www.wma.net/en/30publications/10policies/b3/.

[15] Council of Europe. Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research. 25 January 2005.
http://conventions.coe.int/Treaty/en/Treaties/Html/195.htm.

choice, the supervising judge prefers, wherever possible, the spouse that is not legally separated, the cohabitant, father, mother, son or brother or sister, fourth degree relatives') as well as in the law on 'Provisions with regard to the taking and transplant of organs and tissues' (which in article 23 foresees that the following are legitimated to oppose the removal of organs in writing 'the non-separated spouse or the common-law spouse or, should this not be the case, the eldest children or, should there not be any, the parents'[16]).

It is to be hoped that in the next review of the legislation on clinical trials, which will become necessary following new community provisions[17], the problem of clinical trials with persons incapable of expressing consent is tackled in such a way as to not only give sufficient protection for such persons, but also to not hinder their participation: the exclusion from the possibility of taking part in experimentations in fact entails also their exclusion from the possibility of receiving the benefits that those clinical trials could bring.

Lastly, it must be noted that in the version approved on 18 May 2014[18], the Code of Medical Deontology foresees consent through a legal representative for 'incapable' persons in art. 37, which is included in title IV 'Information and communication. Consent and dissent' (mainly dedicated to prevention, diagnosis and therapy). In art. 48 (included in title VII 'Research and clinical trials) it is furthermore stated that 'in the case (...) of an incapable person experimentation is allowed only for preventive or therapeutic aims relative to the existing condition or its evolution').

3. Recommendations

In the human, medical and social perspective and in the light of the values and principles outlined in the document, the NBC makes the following recommendations.

1. The dementia patient must be recognised as a person in every stage of their illness. The condition of unconsciousness or relational difficulty cannot justify any form of discrimination or stigmatisation.

2. Research (in palliation too), prevention, therapies and assistance for sufferers of dementia must have an important role in healthcare policies.

3. Studies must be promoted on the modalities of communication with the dementia patient and on the ascertainment of the level of consciousness. The autonomy of the patient still able to take decisions must always be valorised and taken into the utmost consideration. Should the decisions be taken by the caregiver, they must, within the criteria of reasonableness, always respect the system of values, convictions and orientations that the patient expressed during their lifetime.

[16] Act No. 91 of 1 April 1999. Provisions regarding the taking and transplant of organs and tissues. Official Gazette of the Italian Republic – General Series 15 April 1999, No. 87.
[17] European Parliament and the EU Council. Regulation (EU) No. 536/2014 of the European Parliament and Council, of 16 April 2014, on clinical drug trials for human use and which repeals directive 2001/20/CE. Official Gazette of the European Union of 27 May 2014, L158: 1-76.
[18] Federazione Nazionale degli Ordini dei Medici Chirurghi e degli Odontoiatri (FNOMCeO). Code of medical deontology. 18 May 2014.
www.fnomceo.it/fnomceo/downloadFile.dwn?id=115163&version=7.

4. Undue forms – valid for any type of patient - of disproportionate treatment or therapeutic abandonment must be avoided and all the more reason for patients not able to express their own will or if aimed at the reduction of healthcare costs. Proper access to palliative care must be guaranteed as in the case of other pathologies.

5. Integrated flexible socio-healthcare assistance and a specialised training of healthcare personnel, social workers and caregivers must be promoted, in order to improve the consideration of the needs of the dementia patient. Adequate practical and economic support must be foreseen for those taking care of dementia patients, a role that is often carried out by patients' families. Research and the use of the new healthcare technologies must be encouraged, as long as they are 'additional' to and not 'substitutive' of human assistance which is considered indispensable.

6. Information, professional training and social awareness must be implemented in favour of dementia sufferers, with campaigns by the Ministry of Health for social awareness to the right/duty to social inclusion and to the importance of solidarity, with specific reference to dementias. In particular the application of the United Nations Convention on the Rights of Persons with Disabilities must be promoted to patients with dementia.

7. Hopefully from the normative point of view the problem of clinical trials with persons incapable of expressing their consent will be dealt with in such a way as to not only provide adequate safeguards for such people, but also to foster – wherever possible – their participation, considering that experimentation can be translated into real benefits for their health.

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