

PRESIDENZA DEL CONSIGLIO DEI MINISTRI

SECRETARIATO GENERALE

N. 8



Italian National
Bioethics Committee

Opinions
2013 - 2014

ISBN 978-88-9088-200-6



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DIPARTIMENTO PER L'INFORMAZIONE E L'EDITORIA

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SECRETARIATO GENERALE
Comitato Nazionale per la Bioetica

OPINIONS

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Special thanks to Dr. Loredana Persampieri, Domizia Di Maggio and Nicolò Messina for their valuable and generous contribution.

The mandate of the National Bioethics Committee has expired in September 2013 and has been renewed with dPCM 27 September 2013.

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Presidenza del Consiglio dei Ministri



**HUMAN RIGHTS, MEDICAL ETHICS
AND ENHANCEMENT TECHNOLOGIES
IN MILITARY CONTEXTS**

22 February 2013

Presentation

For the first time the NBC deals with an issue related to ethics/bioethics in a military context. The Committee began to tackle this issue during the plenary session of 15 July 2011 upon listening to what was said by Col. Gaspare Schiavone, Office Chief of Army Logistic Command, Office for Logistic Operations, and Col. Paolo Astorre, Head of Medical Oncology of the Celio Military Hospital, delegated by Lieutenant General Rocco Panunzi, who had been invited to participate but was not able to take part in the work.

To tackle the problem of the possibility of limiting the use of arms, does not mean to justify war or endorse militarism. There is nothing further from ethics than the openness to give and receive the death that war imposes. It is nonetheless the task of ethics to curb human aberrations, in the hope that limit after limit, reflection after reflection, their elimination may be achieved. This has happened in many Countries with corporal punishment and the death penalty. Can the same happen with war? We are acquainted with the role that humanitarian associations, international organisations and pacifist movements have been playing in this field for some time now. It is appropriate that bioethics should also reflect on the role of the doctor, the type of arms used and the psycho-physical conditioning that the military are subject to. Keeping silent on these issues could mean a scornful repudiation of war, but also the fear to touch a sector, like the condition of the military and their duty to obey, which generally the logic of power or the easy rhetoric of the absolute duty to defend the fatherland tend to exclude from any control and external intromission.

Considering the range of the issues that arose concerning ethics and bioethics in a military context, the working group, coordinated by Prof. Salvatore Amato and Dr. Riccardo Di Segni, reached the conclusion that it is a difficult context to assess completely and exhaustively in one Opinion. Within the context of the numerous problems arising, the working group decided to focus the attention on enhancement in a military framework. Furthermore, this profile was collocated in a wider reflection on the subject of enhancement that the Committee was carrying out also with reference to other sectors, particularly that of cognitive pharmacological enhancement. Well aware of the complexity of the argument and on the basis of the study of the literature and documents available, the coordinators of the group pre-

pared a draft which was first discussed by the group and then in the plenary session.

In a still very uncertain panorama, but characterised by a singular convergence of interests and agreements for collaboration between industry, research bodies and military institutions, the hypothesis is presented of an increasingly engineered soldier removed from the ordinary citizen. ‘Enhancement’ technologies have been employed on this type of soldier that can be defined as ‘strategies to create human capacities going beyond the normal biological variability, by means of modifications of the human function’, among which surgery, genetic modifications, neuronal stimulation, enhancing drugs.

Starting from the shared assumption of the repudiation of war, the NBC expresses a general judgment of ethical disvalue on the specific subject of enhancement technologies in a military context. Many of these technologies represent a risk both for the subjects exposed to them and for the civilian and military adversaries, which goes beyond the limits foreseen by the international law in force related to military operations and war.

The Committee is nonetheless aware that the technological evolution on the one hand and military needs on the other will move more and more towards the adoption of some of these technologies. Concerned about these developments, the NBC considers it necessary that for all technology in such a context, the conviction be affirmed with greater emphasis that a number of fundamental bioethical principles cannot be derogated: the principle of dignity and the physical, psychic and ethical integrity of the military, the principle of non-harmfulness, the principle of autonomy, the principle of equality. To this end the Committee recommends, at a national and international level, the setting up of multidisciplinary commissions similar to ethics committees, constituted not only of military, who might ascertain the compliance with these principles at the various levels, checking the clinical trial protocols, the modalities used to obtain informed consent, the reversibility or non-reversibility of the effects. In the framework of this lies the difficult balance between the duty to obey, the secrecy to which the military is bound and the respect for his or her fundamental rights.

The document, drafted by Prof. Salvatore Amato and Dr. Riccardo Di Segni, was debated in the working group, at which the following participated: Profs. Luisella Battaglia, Lorenzo d’Avack, Marianna Gensabella, Assunta

Morresi, Laura Palazzani, Monica Toraldo di Francia, Giancarlo Umani Ronchi. The Opinion was approved with a majority vote by Profs. Luisella Battaglia, Adriano Bompiani, Bruno Dallapiccola, Lorenzo d'Avack, Riccardo Di Segni, Silvio Garattini, Marianna Gensabella, Laura Guidoni, Assunta Morresi, Andrea Nicolussi, Laura Palazzani, Vittorio Possenti, Monica Toraldo di Francia, Giancarlo Umani Ronchi. Profs. Cinzia Caporale and Grazia Zuffa abstained. Profs. Salvatore Amato, Francesco D'Agostino, Maria Luisa Di Pietro, Demetrio Neri and Lucetta Scaraffia were absent at the meeting but expressed their agreement with the text. Prof. Carlo Flamigni wrote a personal remark.

The President
Prof. Francesco Paolo Casavola

Preamble

The indispensable premise to this document is that the NBC tackles this subject starting from the shared assumption of the repudiation of war ‘as an instrument of aggression against the freedom of other peoples and as a means for the settlement of international disputes’ decreed by the constitutional text (Art. 11); of war defined by the United Nations Charter (San Francisco 26 June 1945) as a ‘scourge’ from which to preserve oneself with the commitment to peace.

This solemn statement does not imply the renunciation of defence from violence by any aggression whatsoever, but instead makes it obligatory to take preventive measures to avert armed force - where possible - and to repress it, with suitable proportionate means, should it be brought into effect.

These principles - now firmly enshrined in international and national law (a hard-fought achievement after centuries-old and bloody experiences) - oblige the sovereign states to keep their armed forces active, and equipped with the suitable instruments to react to offence, to neutralise it, to induce the aggressor to give up their objectives and if necessary - with the intervention of international courts should the aggressor be an external state - to compensate the Country being attacked for the damage caused.

In this very general scheme, according to which the debated question of the so-called ‘just war’ was also formulated - identified back in the Middle Ages - and after the uncontrollable dimension of the ‘Great Armies’, constituted by the compulsory recruitment of whole demographic classes of the male population in the XIX and XX Centuries, an ‘Armed Force’ has in many Countries substituted all this, made up of persons who voluntarily enrol in the exercise of a military profession, which - for their whole working life or parts of it - constitutes above all the work (contractualist employment) of young people, who for different reasons apply for enrolment and are selected according to physical, cultural, moral and behavioural characteristics, etc. established by the specialised ‘technicians’ in military art, who make up the decision-making summit of the Armed Forces.

‘Military sociology’, a branch of general sociology applied to the military world, has widely examined the various models according to which the organisation of the Armed Forces is realised, pointing out which behavioural requirements of the recruits must be covered to confer ready and efficient operational skills to oppose armed conflict to those very Forces.

The present organisation process that has been used in recent decades, coming also from the experiences gained in World War II, regional conflicts and terrorism, sees the establishment of two basic parameters:

1) the development and practical application of all those innovative techniques that might increase the defence/offence quotient for what is globally understood as ‘armament’;

2) the increased and progressively more sophisticated care in the preparation of the ‘human factor’ and that is of the Officers (who have increasingly become true experts in the various disciplinary fields involved) and the soldiers who become more and more ‘executive’, with high levels of professionalism.

The military Health Corps, which has integrated the Armed Forces for Centuries, superintends every aspect of health protection.

The considerations of this document are based on these factors in particular.

1. The question of enhancement in the conferral of a high professional level

The human enhancement techniques concern various fields of scientific experience and take on a plurality of aims. In this document the NBC sets out to analyse that particular profile represented by the use of these techniques for military purposes¹. In this choice the Committee is aware that the data and information to work on are necessarily approximate, as an evident reticence exists on such a delicate subject by every state to reveal its strategies and declare its intentions. Nevertheless, in the last ten years, this problem has arisen more and more frequently not only in essays and newspaper articles², but also in various official documents of the National Research Council (NRC) of the United States which have looked at the single aspects of this composite reality: non-lethal arms³, the potential of the use

¹ For other aspects of enhancement see the Opinion on *Neurosciences and pharmacological cognitive enhancement: bioethical profiles* approved by the NBC on 22.2.2013.

² For example W. Pinkus, *Study Urges Using Neuroscience to Improve U.S. Soldiers’ Performance*, in “Washington Post”, Monday, May 18 2009.

³ NRC, *An Assessment of Nonlethal Weapons Science and Technology*, The National Academies Press, Washington DC 2003.

of biomaterials and information technology in distance medical care⁴, the neurosciences⁵, genetics, nanotechnologies and pharmacology⁶. Referring to these documents the Royal Society of the United Kingdom wrote the report on *Neuroscience, Conflict and Security* in February 2012.

It thus seems appropriate to begin a reflection that attempts to identify the minimum essential ethical margins that must be claimed, in any case, also within a context that often seems far from any possibility of control and total respect of the fundamental rights of the person. In the words of Canetti, it is difficult not to take cognizance that ‘what in time of peace is banned with the hardest sanctions, here it is not only expected of the individual, but practised *en masse*’⁷. However many theories have been formulated to bring back war within ethical limits and however many international declarations may have been undersigned by the single states, it is difficult to avoid the resigned conclusion that ‘death, violence, suffering remain the trio that best defines war’⁸.

According to some, even the doctor who during wartime occasionally makes the last extreme attempt to reduce suffering, but on other occasions manages to save the wounded from death, finds himself playing a role which in some respects is ambiguous, since he must quickly heal people who are then sent to die or kill once again. The more the doctor works to avoid death the more he fuels it in that perverse game that Brecht describes with painful cynicism, in ‘Me-ti, *Book of Changes*’ and stresses how the predicament of doctors is particular evident in war. They can do nothing to stop war, but only ‘patch up’ the smashed limbs⁹. This judgement is not exact as it is forgotten that the doctor’s specific role is to try and restore health to the wounded or to alleviate suffering.

⁴ NRC, *Capturing the Full Power of Biomaterials for Military Medical Needs*, The National Academies Press, Washington DC 2004.

⁵ NRC, *Emerging Cognitive Neuroscience and Related Technologies*, The National Academies Press, Washington DC 2008; *Opportunities in Neuroscience for Future Army Applications*, The National Academies Press, Washington DC 2009.

⁶ NRC, *Human Behavior in Military Contexts*, The National Academies Press, Washington DC 2008.

⁷ E. Canetti, *Potere e sopravvivenza*, It. tr., Adelphi, Milano 1974, p. 25.

⁸ G. Cosmacini, *Guerra e medicina. Dall’antichità a oggi*, Laterza, Roma-Bari 2011, p. 196.

⁹ Me-ti, *Libro delle svolte*, It. tr., Einaudi, Torino 1997.

Realism would lead us to simply establish the clear conflict between the rules of war and those of peace. Even if we would all like to live in a better world, a sort of ‘furious madness’ comes out in men leading them to deprive themselves, with their own hands, of all the advantages of peace as *Querela pacis* by Erasmus from Rotterdam suggests to us. Idealism does not deny the plausibility of this perspective, but drives us to make a kind of act of faith: to believe in the possibility of the respect of some fundamental principles even during conflicts would mean to offer humanity a chance to change. It is likely that the opportunity will never be taken, but it would be worse if it were never offered. Kant taught us that ‘Some trust in the enemy’s way of thinking must still remain even in the midst of war since otherwise no peace could be concluded, and the hostilities would turn into a war of extermination’¹⁰.

For these reasons, the NBC considers that it is necessary to intervene also in a sector that is increasingly being highlighted, like the possible use of human enhancement technologies in a military context which, if used for offensive potential, would hardly appear to come into the usual canons of bioethics. On the other hand, one must bear in mind that war has always constituted a significant time for experimentation, application and increase of new knowledge in every sector of technology and in particular in those of medicine, from the antiseptics practised systematically in the Franco-Prussian war of 1870, to morphine injections by hypodermic syringe experimented during the American Civil War, from X-rays used during the First World War to the massive use of amphetamines as fatigue and fear inhibitor during World War II and so on. It is likely that the streamlining of distance monitoring and healthcare of soldiers will make it possible to extend the horizons of telemedicine with an effect on the role of the doctor, electronic instruments for the identification of the enemy will open up new prospects to biometry, the use of chemical substances or genetic manipulations to increase attention, memory and the speed of decisions are likely to have therapeutic repercussions. Even without hoping to bring back war within the limitations of ethical control, the analysis of the effects of these new technologies must

¹⁰ I. Kant, *Per la pace perpetua*, Feltrinelli, Milano 1991, p. 27. Referred to by L. Mumford, *Per una civiltà umana*, It. tr., Scheiwiller, Milano 2002, p. 35.

not be neglected in order to be prepared to face the repercussions that there could be on normal relations of coexistence in peacetime. The *dual use*¹¹ theory highlights how difficult it is to trace a clear demarcation line between normality and exception so as to avoid a contorted or negative use of scientific progress.

We know that some of the above mentioned technologies are already being experimented in some Armed Forces of other Countries. It therefore becomes ethically important to try and define the distance separating the exception from normality and, above all, to ascertain to what extent it is still possible to apply the traditional categories of natural/artificial, enhancement/deterioration, benefit/harm, autonomy/coercion to these technologies.

The NBC has already partly dealt with these issues in the documents on *Neuroscience and human experimentation: bioethical problems* of 17 December 2010, *The identification of the human body: bioethical aspects of biometrics* of 26 November 2010, *Nanosciences and nanotechnologies* of 9 June 2006, *Ethics, health and new information technologies* of 21 April 2006. Now it sets out to examine to what extent these technologies might, through military use, take on particular connotations that coerce the ethical limits of experimentation and affect personal integrity and human identity more and more deeply. From this point of view, the *dual use* theory takes on particular importance since the experimentation and utilisation of these technologies, even though not having a strictly therapeutic nature, is presented as an instrument for the protection of the integrity of the soldier, who will feel less fatigue and stress, will control his actions better, will be treated more readily and appropriately and will distinguish friend from foe without making mistakes. While the use of ‘smart bombs’ constitutes, or is at least presented as such, a reduction of the destructive outcomes of war, also the

¹¹ The term is thus defined, according to the fields of application: “*Dual-use describes something that can be used for two purposes, such as for civilian or military purposes*”; “*dual-use items*” shall mean items, including software and technology, which can be used for both civil and military purposes, and shall include all goods which can be used for both non-explosive uses and assisting in any way in the manufacture of nuclear weapons or other nuclear explosive devices”. Cfr.: “*Setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items*” COUNCIL REGULATION (EC) No. 428/2009, 5 May 2009; “*A comprehensive strategy on how to minimize research misconduct and the potential misuse of research in EU funded research*” in the website [ftp://ftp.cordis.europa.eu/pub/fp7/docs/misconduct-misuse_en.pdf](http://ftp.cordis.europa.eu/pub/fp7/docs/misconduct-misuse_en.pdf).

biotechnological enhancement of the ‘engineered soldier’ could appear as a way to reduce the number of victims. The idea of an increasingly scientific and less bloody war emerges, where the pills should substitute the bullets (*pills instead of bullets*) and the non-lethal arms should take on a predominant nature. By means of nanotechnologies and neurosciences, the future arsenals will be devised to induce incapacity rather than death, bringing about panic, depression, psychosis and delirium in the enemy.

The NBC does not intend to examine how credible these scenarios are, nor does it have the means to do so. It sets out to begin a reflection on what the possible costs to be paid are to realise the instruments that are recommended to pass from ‘bench to bunker’¹². How is or how will the experimentation be carried out? To what point are the effects that will be caused reversible? To what extent will the utilisation of the body as an ‘arm’ or a ‘machine’, devised, modelled and enhanced exclusively in the light of military needs have repercussions on human identity? Insofar as the declared effect consists of putting the military in the best possible condition to defend his own and his Country’s safety, the further effect would result in the rise of the efficacy of aggressive potential. This impossibility to keep the defensive element distinct from the offensive one belongs to any form of military training or armament improvement, but in this case the conditioning is particularly deep as it is not just a question of building new destructive machines but of forging new ‘machine men’ who are more and more distant from normal men, but also more controllable or rational subjects.

There is also another question that arises. As well as the problem of the reversibility of the conditioning effects in the military, it becomes crucial to think of the impact of all this on the civilian population, both during the conflict and in the difficult phase of the return to post-war normality.

In short, the general problem appears once again of war that marks the history of man increasingly radically, deeply modifying single lives: every war, with whatever means it is waged. The context of future war would essentially question the right to life but also the right to the integrity of the body and the psyche, which are increasingly manipulated for different needs

¹² J. Bardin, *From Bench to Bunker. How a 1960s discovery in neuroscience spawned a military project*, in “The Chronicle Review”, July 9 2012.

by the protection of health or the search for wellbeing. For this very reason, it is appropriate to make an in-depth evaluation of the demand for new technologies of military equipment from science, to ask them the same questions that bioethics asks science. Their answers should be on the consented limits of experimentation on man, informed consent, the duty for transparency, etc. exercised in a military context. The British Medical Association has stated that “*working to enhance national security may not always be compatible with the fundamental tenets of medical ethics*”¹³. The NBC is aware that the military must undergo a number of restrictions of his own rights in the name of the duty to obey; nonetheless, the NBC considers that it is indispensable to support the existence of the military’s inalienable right to the same guarantee procedures that regulate experimentation on man.

2. What technologies are being discussed: the need to make distinctions

The above considerations lead us to state that, if by ‘human enhancement’ we mean to the letter and generically any form of intervention that tends to improve the corporeity, the mind or the single individual capacities, it is undeniable that this is nothing new nowadays. There are historical and classical means of such ‘enhancement’. Some act on physical performance (training) or resistance to illnesses. During the American revolution, George Washington had his troops vaccinated against smallpox (as was done empirically before Jenner) as his men were much more prone to the disease than the English. Other systems tend to improve the soldier’s performance, decreasing the traumatic impact of the direct clash with the enemy and its ethical implications: from the language, that presents war operations as a work of pacification, to the physical presence (bombings at a distance with the metaphors of ‘surgical’ precision of ‘smart bombs’), to social distance (demonisation of the enemy, group loyalty contrasted with the radical hostility of the alien)¹⁴. An important and consolidated role is that of drugs and substances like alcohol, which reduce anxiety, fear and control. In high

¹³ BMA, *Boosting your brainpower: Ethical aspects of cognitive enhancements*, London 2007.

¹⁴ P. Lin, *More Than Human? The Ethics of Biologically Enhancing Soldiers*, IEET, March 28 2012.

doses caffeine was and continues to be used to resist sleep. In World War II amphetamines were widely used to resist tiredness and fatigue. During the war of the Falklands the English soldiers used Temazepam to guarantee better rest at times when they could sleep. In the American army Zolpidem is used as a sedative for the same purposes. These ‘first level’ interventions within the limits of a discrete use and in traditional circumstances (e.g. night patrols, nursing night shifts for the seriously wounded, etc.) are less problematic from the ethical point of view.

The new element presented by some and which instead represents a problem, consists not only of the increase of today’s genetic, pharmacological and micro-electro-mechanical possibilities of enhancement which would make it possible to produce effects that were unimaginable in the past, but also in the forecast of a simultaneous and combined application of all these technologies to envisage the design of a sort of “*mech-warriors*”¹⁵; “machine men” further and further away from the normal man. A prospect is beginning to appear, for now only hypothetical but not unreal, which could have serious repercussions on the way of understanding human identity, making it very difficult to identify the threshold of ‘normality’ from which to formulate a stable and shared ethical horizon. It could be said that there is no need to predetermine this horizon, insofar as the decisions are entrusted exclusively to individual choices according to the principle that ‘if it were not good for you, then it should not be enhanced’¹⁶. In the case of the military however, enhancement would take place also in the interest of the community of belonging and/or of that defence with arms (e.g. the squad of belonging or particular equipment with arms suitable for specific tasks) for which reason it is not possible to avoid the problem of the level of sacrifice that can be requested - at least of some - and of the conditions that might legitimise it.

Some maintain, moreover, that in a sector in which many aspects of human identity are questioned it is impossible to entrust the problem of ethical legitimacy exclusively to the right to self-determination, since there is always an evident social repercussion in any way whatsoever of being and

¹⁵ Lin, cit.

¹⁶ J. Harris, *Enhancing evolution: The ethical case for making better people*, Princeton University Press, Princeton NJ 2007.

acting. In this case, however, the relationship between good and evil would not concern single actions or the use of specific armaments, but the very existence of human beings that are designed and manipulated as if they were ‘arms’, also by means of established modifications of their corporeity. From the point of view of human rights the problem arises of the moral and juridical statute of these particular forms of ‘post-human’. Should we exclude these new subjective situations from the protection of human rights and think of new forms of responsibility and protection, ‘the so-called post-human rights’, or must we foresee a diversified application of human rights today recognised and in force between ‘enhanced’ and ‘non-enhanced’ subjects¹⁷? From the point of view of international law the problem arises of how to define these interventions on the human body, should they take on an exceptional and irreversible nature. Could the creation of these new ‘bio-mechanical fighters’ be compared to the creation of new ‘biological agents’ coming under the prohibitions laid down by the Convention on the use of biological weapons?

In any case, the bioethically complex point is represented by the possibility to identify plausible parameters by which to establish the difference between ‘improvement and/or optimisation’ and ‘enhancement’ and/or change¹⁸. Our proposal is to consider all those interventions as forms of ‘enhancement and/or change’ that push the bio-physical capacities beyond the typical level of the species and beyond the statistically normal margin of functionality for single individuals¹⁹, nonetheless bearing in mind the reserves of a number of bioethicists who question not only the possibility of making a convincing distinction between the two concepts, but also the value of this distinction for the formulation of judgements on the licitness/illicitness of the different practices. It must be highlighted that the main context in which these bioethical reserves lie is that of the neurosciences, in which the definition of normality has controversial margins, while in a context of physical efficiency the above criterion is more widely accepted even if not unanimously.

¹⁷ A. Buchanan, *Moral Status and Human Enhancement*, in “Philosophy & Public Affairs”, 2009, 37, 4.

¹⁸ M.J. Sandel, *The case against perfection*, in “*The Atlantic Monthly*”, 2004, 293, pp. 51-62. In Italian *Contro la perfezione. L’etica nell’età dell’ingegneria genetica*, Vita & Pensiero, Milano 2008.

¹⁹ N. Daniels, *Normal functioning and the treatment enhancement distinction*, in “Cambridge Quarterly of Healthcare Ethics”, 2000, 9(3).

In the analysis of the new systems it is useful - even in the awareness of the problems of the definitions in this context - to distinguish between the ‘optimisation’ of human performance (*Human Performance Optimization*, HPO) which refers to ‘strategies to sustain performance before stress factors putting it at risk, for example, selection, training, nutrition, rest, equipment, command’ and ‘enhancement’ of the human performance (*Human Performance Enhancement*, HPE) and that is: ‘strategies to create human capacities that go beyond the normal biological variability, through modifications of the human function (e.g. surgery, genetic modifications, pharmacology, neuronal stimulation)’.

The traditional physical and psychological training programmes come more specifically into the context of optimisation systems, in order to develop the mental capacities of leadership, physical, emotional and mental control of stress in situations that demand high performance levels, attention and professional excellence. That sort of ‘ultraview’ realised by *Warfighter Refractive Surgery* poses greater doubts of classification, to the limits of natural human potential, and carried out by the American armed forces on over one thousand air force pilots and over 230 thousand soldiers to obtain a visual capacity of fifteen tenths, making it possible for example to see a fly nine metres away, with obvious advantages of being aware of and avoiding dangers.

In the context of real enhancement the different systems can be considered according to the technologies or objectives. These situations are very different also from the point of view of the actual possibility to be realised. In many *National Research Council* studies scales of feasibility are foreseen that range from three to twenty years. We are therefore going ahead, even if starting from reliable scientific data, in the horizon of probability and at times of only possibility. The NBC does not intend to examine the single perspectives, but to look at the bioethically most important points for human identity which would derive from an overall framework.

3. An analysis of some enhancement methods

Bearing in mind these premises and underlining the fact that for the moment it is more a question of hypotheses and studies being carried out rather than real possibilities of application, it is appropriate to distinguish among these technologies:

Drugs:

In this field there is a constant transfer of notions coming from practice and clinical trials to the particular military situations.

The Ampakines, the subject of research in memory and attention deficits, are studied for their possible effects in the control of sleep and other situations of neurological stress. Again with regard to sleep, which seems to be the field being studied most nowadays, the possible uses of Modafinil used in narcolepsy are being investigated, and of Hypocretin by nasal spray, the effects of which are known in sleep disorders in trypanosomiasis. In the US army, Modafinil is already being used for pilots during long missions and Setraline hydrochloride is prescribed for troops undergoing lengthy combat exposure to reduce stress and risk of depression²⁰.

From the use in patients suffering from dementia to its use in memory enhancement (Methylphenidate). This is a developing sector that concerns 'cerebral plasticity': drugs that act on the synaptic connections and which would be more promising than those already used like Modafinil and Donezepil. They are expected to have an effect in the improvement of the memory, attention and cognitive performance. They could also have the effect of weakening or cancelling previous memories, and in such a way be used to eliminate distressing or embarrassing memories, or to reduce the enemy's defence capacities.

Beta-blockers and serotonin inhibitors act on and can be used on mood, anxiety and self-perception; oxytocin on empathy, trust and moral decisions and the suppression of testosterone²¹.

In another perspective outside the neurological field are the anabolic steroids used in the treatment of sarcopenia and osteoporosis in the production of great muscle mass, a problem that greatly involved sport before hitting the military context. The masculinisation of the woman by androgens to enhance aggressiveness must also be considered.

The treatment of anaemia with recombinant erythropoietin could open the way to the creation of organisms with increased oxygenation capacities in prohibitive conditions.

²⁰ *Opportunities*, cit., p. 55.

²¹ *Emerging Cognitive*, cit., p. 32.

The use of nanoparticles for elective medication would increase their potential use in specific fields.

Genetics:

The knowledge of genetic mechanisms that are at the basis of certain pathological situations suggest possible uses that could be realised with genetic manipulations (by means of viral vectors or implants of genetically modified cells) or with specific drugs for the temporary inhibition of certain functions. For example congenital analgesia, due to a genetic mutation of the SCN9A gene makes patients insensitive to pain; it is a rare and dangerous childhood disease. But its mechanism could be replicated to create subjects that are insensitive to pain and therefore extremely useful in military conditions with a high exposure to painful factors. The myostatin gene could be manipulated to increase muscle mass²².

In other words, genetic knowledge might be used to identify capacity, predispositions, susceptibility to catch certain diseases and to be resistant in exceptional conditions²³.

Neural stimulation:

Electrical brain interfaces made up of microelectrodes already exist. Inserted into the cerebral cortex they can be used to give visual information in blind people or to give motor stimuli in paralysed patients. Implanted into the subthalamic nucleus or the globus pallidus they are useful in the treatment of Parkinson's disease or other neurological diseases, depression, epilepsy, instead of or with better effects than drugs. Alternatively to electrodes transcranial or magnetic vagal nerve stimulation is however also considered. Seriously wounded soldiers can derive benefit from these new treatments, but we should also consider the potential of their development on healthy subjects. Distance controlled stimulation should be effective in resistance to stress, pain and tiredness, in speeding up reactions, increasing memory capacity, creativity, etc.; in giving sensations of pleasure/pain, grat-

²² K.E. Friedl, *Overview of the HFM-181 Symposium Programme Medical Technology Repurposed to Enhance Human Performance*, NATO OTAN RTO-MP-HFM-181, pp. 1-20.

²³ *Opportunities*, cit., p. 20.

ification or refusal, that directly affect decisions and behaviour²⁴. In other words, control technologies are being studied that are placed inside specialised helmets able to give information at a distance on the state of health and the reactions of the fighters with the possibility of suppressing undesired reactions or to enhance the desired ones²⁵.

Stem cells:

From the sectors of the clinical use of marrow, corneal, bone and spine repair, their use can be foreseen in the treatment of serious invalidating injuries, but also a theoretical cerebral use to increase capacities and speed in mnemonic functions and learning.

Special surgery:

From the field of ablative neurosurgery interventions, selective surgery for the control of sleep and attention span can be prefigured.

Corneal surgery, also by laser, increases visual capacity.

Prosthesis and information technology support:

Prosthetic limbs are envisaged to give superhuman strength, performance and stamina; eye prostheses for sensitivity to radiations that are not normally perceptible; hearing systems for auditory capacities beyond the normal human thresholds.

From the point of view of objectives, the enhancement offered by all these systems is expressed in an overcoming of the normal human capacities in the fields of sight, movement, tolerance to extreme temperatures, in hypoxigenated arid climates; in the increase of memory, the possibilities and speed of learning, resilience to stress, loss of sleep, pain and tiredness. The application of a *personal status monitor* to the body should make it possible, by means of the use of *neuro-imaging* technologies, to visualise the regions of the brain so as to guide the cognitive and decision-making processes or to enhance, with the interface connection with electronic devices, visual ca-

²⁴ Friedl, cit., E. Williams et al., *Human Performance*, JASON The MITRE Corporation McLean, Virginia 2008.

²⁵ *Opportunities*, cit., pp. 76 and 84.

capacities and to keep a centralised control of the operations zone. The application of this electronic distance monitoring increases the role of “telemedicine” (*digital medicine*) to keep the physical-pathological conditions of the soldier under control (heartbeat, body temperature, blood pressure, electrocardiograph map) and to even carry out surgery at a distance (*remote telepresence surgery*).

4. The bioethical problems

The NBC considers that the starting point of the bioethical reflection on this issue must be the adherence to the general criteria and principles of bioethics and biolaw internationally recognised as being aimed at the protection of the dignity and fundamental rights of man. A reflection must nonetheless be made on the application of such assumptions to that particular ‘ethos’ characterising on the one hand the professional soldier during his enlistment, on the other hand characterising the just as specific ‘ethos’ of the medical profession in whatever context it is practised.

It is therefore a question of reflecting on the argument according to that ethics of the professions, which makes up not only the traditional deontology of conduct among professionals of the same discipline but constitutes a norm of conduct due towards others.

As said above, the first and basic distinction concerns the difference between the optimisation procedures of performance and those claimed as a real enhancement, between the improvement of the subjective conditions and the change of the models typical of the species. The use of the recently acquired scientific knowledge in the medical field, with particular reference to the neurosciences, opens up new and more powerful means by which to control the state of individual health, the reactive capacities and modalities in conditions of stress. More sophisticated selection mechanisms and training programmes derive from this. These optimisation procedures alone, which are part of the training programme aimed at shaping more resistant and motivated people, could pose bioethical problems, owing to the tough operations foreseen in some of the training. There may only be a fine line separating this from the enhancement procedures and the difference blurred. But the examples of the huge case record mentioned above show that one can speak of enhancement when the objective consists of creating subjects who go beyond the normal biological variability, by means of mod-

ifications of the human form and function, above all if they remain after the period of military life. Until now the use of artificial means had been used in the treatment of pathologies, to bring back the pathological to the physiological; instead this is a question of bringing the physiological to the ultra or super.

It is in this more specific context that there must be a more careful bioethical control, in the awareness of the vast range of possible risks.

One aspect of the problems is not new. The sports environment where use is made of anabolic steroids, or that of schools and universities where drugs are taken to improve the brain's performance present situations with a certain similarity.

In its Opinion on Ethics, Sport and Doping (25/3/2010 Conclusions and recommendations), this Committee stated with regard to the use of doping in sport:

1) The judgement on the ethical disvalue of the recourse to doping, which this document sets out to reaffirm, is based on a number of reasons, which range from the need to safeguard the athletes' physical health and their real autonomy of choice to the moral values intrinsic in sport and to the preservation of the meaning of sport in the collective imagination. Although there are different assessments of whether these reasons are able to overcome a certain rational scrutiny, it does not appear however that the reasons given by those against the prohibition of doping are completely convincing or devoid of limitations.

2) The sporting spirit, as such, is the spirit of a competition in which athletes face each other who, streamlining their physical capabilities, through training, effort, sporting intelligence and willpower, are able to express an essential aspect of our common human identity, that of "merit", which does not only depend on the natural gifts each of us receives from birth, but especially on how each person strives to use them in building their identity (particularly, the athlete's identity).

Nevertheless, this analysis must highlight the differences and specificities of the military case as well as the analogies. To create Olympic champions is not the same as creating efficient soldiers with better possibilities of quickness, sharpness, identification of danger, for the protection of themselves and their division too. The importance must also be stressed of an education aimed at fostering reciprocal solidarity and support in emer-

gency conditions, among those belonging to the same base unit²⁶. In war a spirit of noble competition and an importance of ‘merit’ can undoubtedly exist, but these values are repressed by a different concept of contemporary military art and by more urgent needs to save one’s own side to the detriment of the other. In war, which is essentially different from any sporting competition, there is a tendency to neutralise the adversary, even at the expense of his life. Those who fight however jeopardise their lives. The horizon is different also for other reasons. In sport the resorting to doping derives from choices and answers to personal and/or team interests, whereas in a military context it mainly answers to a general interest, which is that of preparing the best conditions of responsiveness above all of defence (see Art. 52 of the Constitution), but if necessary of counterattack. In the context of sports, moreover, as in other bioethical contexts, a possible argument in favour of the liberalisation of some forms of enhancement could be represented by the need to bring to light and to regulate conduct which would otherwise remain clandestine. In the case of doping however, the NBC’s orientation has been that of not considering this argument as being sufficient. In the military case, the context is evidently different and informed consent could not always be requested when dealing with substances covered by military secrecy. Furthermore, in the military case, as already pointed out, the greatest efficiency entails as much the increase of defence instruments as the offensive ones. A subject who is more insensitive to pain is less vulnerable, but can also be less sensitive or more indifferent to the suffering of others. If doping already tends to clearly separate those using it from all the others, biopsychic enhancement could create even more radical divergences in the way of living and experiencing human relationships, as is envisaged by some for the return to civilian life. In any case it seems little suitable to follow the way, as previously mentioned, of formulating the confirmed rights of the post-human; moreover, every time that an incompatibility were to be manifested between the traditional way of defining the rights of the person and the models of behaviour induced by enhancement we should affirm that a moral violation exists. While it is acceptable to increase the spheres of responsibility of ‘enhanced’ subjects

²⁶ Friedl, cit., § 1.5.3.

(the Italian legal system for example sanctions the recourse to violence of a boxer more seriously or by whoever does martial arts), a diversification in the exercise of rights would be unacceptable as much in favour (privileges, exemptions from responsibility, special courts) as to the disadvantage (limitations of relationships, exclusion from certain positions) in the military condition.

From the biojuridical and bioethical point of view, it is indispensable to also tackle the problem of the limits of admissibility of these techniques: to what extent and on what basis can they be imposed. These are interventions which, in a strict sense, have no therapeutic nature, but in a broad sense this does not apply in the case of preventive vaccinations, under the aspect of the improvement of health ‘defences’ and the possibility of survival in conditions of foreseeable exposure on duty to microbial agents or known viral pathogens²⁷. This way seems legitimate to the extent to which the parameter adopted, pre-eminent with respect to any other need, is the interest in the protection of the soldier’s life and health, as long as informed consent is obtained, as we shall see below, and effects are not foreseen that are so radical and irreversible as to jeopardise his return to a normal social life. In this case as well the usual rules of preventive medicine for everyone are valid.

Particular problematic profiles are instead represented by:

a) the experimental aspect of some of these interventions, exacerbated since they are carried out on healthy subjects, without the ‘publicity’ of specific protocols and suitable external controls, to achieve results that often have no definite established threshold (as in the case of the return to normality after an illness), but feel the effects of the ideological conditions of political aspirations of the single Countries. This is a field in which the experimental dimension could reach extreme levels that are hard to reconcile with the respect for human dignity.

b) the physical and/or psychological effects to be obtained. The extraordinary capacities acquired by some types of performance can be at the

²⁷ Moreover the very vaccinations of the military are the subject of debate, and also of media controversy, owing to the risks that they would involve for health when administered in a great number, close together and with unsafe excipients.

expense of other types of performance and capacities²⁸. They can create a figure of a soldier who is not only professional, but an automatic fighting machine, detached from civil society. The awareness that a person treated in this way acquires their own capacities or incapacities can disturb the psychic balance, with mechanisms that go from the exaltation of their own image to refusal and even suicide.

c) the problem of the persistence or reversibility of the effects. The effects can be short term, in the immediacy of conflict or the training process, but can persist over time and sometimes be irreversible, in body and mind. One must ask: what kind of problems can the induced modifications, if permanent, pose when returning to civilian life? If these are advantages, how can competitiveness with the normal members of civilian society be managed? If there has been a modification of the psyche, what permanent consequences can be envisaged towards third parties?

In a normal context of clinical trials the general rules based first of all on informed consent are enforced. The NBC expressed its standpoint on this in its Opinion on Neurosciences (conclusions § 4): ‘The studies and research in the neurological sector must still comply with the requirements of ethics inherent in any testing on human subjects, found in risk-benefit assessment, in informed consent and the authorization of the use of results, balancing the protection of ‘privacy’ with the requirements of advances in knowledge and societal needs. A particularly important role is played by ethics committees that will have to acquire specific expertise in neuroscience. It is hoped that the scientific community will formulate codes of conduct, in order to ensure the growth of awareness and shared ethical behaviour’. The question is whether in a military context these interventions, already aggravated by the uncertainty and high variability of the results, especially long term ones, can justify partial or total departures from the principle of consent. The NBC’s opinion is that one cannot depart from this; moreover it could be illusory to think that in a context like the military one, based on the hierarchical chain and discipline, it is possible to exercise a normal right of consent or dissent. Even though these are rather particular

²⁸ Friedl, cit., § 1.5.4.

situations, one must start from the assumption that they should in any case come into the context of voluntariness, which furthermore exists and is permitted in a military context. Moreover, so as to limit the possibility of the decision falling on the last and weakest link, it is necessary to activate supervision from above and control commissions in which the presence of experts can be very important in the protection of the individual involved in the experimentation. In any case these must be procedures that, in the opinion of the organs of control, come into the context of the optimisation of the personal bio-psychological performance and not into that of enhancement as outlined above.

The so far accepted codes can be questioned. If the enhanced individuals are in some way a new form of arm, great part of today's international conventions should be revised. People able to stand situations that go beyond the threshold of normality resist pain more than others. And this, in the obvious and shared abhorrence for any form of torture, points to the tragic spiral towards which we could find ourselves going before increasingly refined forms of torture to elude increasingly refined technologies that raise the pain resistance threshold. The protection effect of the soldier would end up by increasing the risks that he runs. The fight against pain (extremely useful in the treatment of pathologies) would in such case end up fuelling new and unforeseen forms of suffering.

In particular there is the problem of the applicability of the international conventions on the use of biological weapons (*The Biological and Toxin Weapons Convention* of 1972) and chemical weapons (*The Chemical Weapons Convention* of 1993). Article 1 of the Biological and Toxin Weapons Convention bans the production and the possession of 'Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes'. By analogy could the systematic use come into this ban of pharmacological 'agents' to build 'enhanced' soldiers, increasing their memory, self-control, resistance to sleep, tiredness, pain and generally speaking their emotions? In this very case it appears evident how difficult it is to distinguish between the defensive aspect, tending to increase security and reduce the suffering of the soldier, and the offensive aspect of the efficiency in giving death. Enhanced soldiers become enhanced weapons, posing international law new and disquieting questions.

It is difficult to exclude that bio-chemical interventions aimed at systematically lowering the normal sensitivity thresholds can bring on indifference to the pain of others and that interventions at a distance of gratification or punishment can reduce the soldiers' moral integrity or their ability to make moral choices, exposing them more and more to the possibility of carrying out actions against humanitarian law and ethics. The conditions can be created for new atrocities against humanity. Also in this perspective the question is whether the exceptionality of the war condition, in which human lives and the survival of a community are at stake, can justify the recourse to extraordinary means.

The specific medical responsibility in all these processes must be stressed; the people who study and develop most of these technologies and who should then apply them to single individuals, selecting the most suitable candidates are doctors. The medical deontology, accepted in a military context, should not however allow departures from the fundamental bioethical principles applied to the medical profession and relative to the experimentation on man, even those in uniform.

Recommendations

Starting from the shared assumption of the repudiation of war, the NBC expresses an opinion of ethical disvalue on the subject of enhancement technologies in a military context. Many of these technologies represent a risk both for the subjects who have to undergo them and for the adversaries, civilian and military, that goes beyond the limits foreseen by the international law in force relative to military activities and war.

Technological evolution and military needs will increasingly press for the adoption of a number of these technologies. In some cases it will be difficult to distinguish between optimisation and enhancement. Conscious of and concerned about these developments, the NBC considers it necessary that for all technology that is not already classifiable as enhancement the conviction be affirmed that some fundamental bioethical principles cannot be derogated:

- a) the principle of dignity and integrity by which all those technologies must be banned that could modify the psycho-physical and ethical integrity of the military for an extended period or permanently;
- b) the principle of non maleficence by which any intervention, even if it did not have immediate effects on health and were not realised in the

exclusive interest of those subject to it, must exclude both present and future harm, even in the perspective of returning to civilian life;

c) the principle of autonomy by which it is always necessary to inform the military of the nature and the risks of the treatment they could be subject to and to respect the autonomy of their judgement. By virtue of the very delicate nature of these situations, the procedures for the format of the informed consent, written and always revocable, should follow the international guidelines for subjects exposed to risks and as specified below in point 2).

d) the principle of equality according to which it would be illegitimate to carry out discriminations in the exercise of rights and in career advancements between those undergoing interventions and those refusing them, and this applies in both conscription and voluntary enrolment.

In support of these bioethical principles the NBC recommends that the Italian Government be promoter of the adoption of the following measures at national, European and international levels:

1. to consider enhancement for military goals in its various possible forms (genetic, pharmacological etc.) as an activity detrimental to dignity insofar as able to modify the psycho-physical and ethical integrity of the subject for extended periods of time or permanently;

2. to set up multi-disciplinary commissions similar to ethics committees, made up not only of military, which might ascertain the compliance with these principles at the various levels, controlling the trial protocols, excluding enhancement interventions and verifying that the other optimisation interventions guarantee the respect of the fundamental bioethical principles, particularly the transparency of the procedures by which to obtain informed consent.

Personal remark signed by Prof. Carlo Flamigni

In an informal meeting with an authoritative member of the Presidency Committee I was asked, very politely but rather peremptorily, to write codicils of dissent shorter than I usually do, also so as not to burden the Committee with excessive English translation costs. This codicil will therefore be very short indeed: I can in no way approve a document that endorses the principle according to which war is an inevitable event (for which it is necessary to prepare in the best way possible, even if respecting a number of

ethical rules) and the existence of an army is a necessary evil. I would just like to recall that in Article 11 of the Italian Constitution it is stated that Italy repudiates war, that Article 52 has been outdated by facts (compulsory conscription no longer exists) and that the defence of the fatherland to which the same article refers to can be entrusted to non-violent means.

Presidenza del Consiglio dei Ministri



**NEUROSCIENCE AND PHARMACOLOGICAL
COGNITIVE ENHANCEMENT:
BIOETHICAL ASPECTS**

22 February 2013

Presentation

In Anglo-American literature the term ‘*enhancement*’ is now widespread to indicate intentional intervention in the alteration of the body and mind in relation to ‘normal’ physical and psychological functioning. Think of the use of psychotropic drugs to enhance memory, to increase intellectual activity, to selectively eliminate unpleasant or traumatic memories, to control unwanted emotional states. It outlines a new sphere of bioethical reflection which calls into question the aims of medicine, the meaning of care, the boundaries between health and disease, between normal and pathological, but also the meaning of human nature and social justice.

The NBC carries forward in this Opinion some thoughts already expressed in previous opinions dedicated to neuro-scientific experiments, doping and aesthetic surgery. The document, after restricting the scope of its investigation to ‘pharmacological neurocognitive enhancement’ briefly outlines the state of the art, noting that at present the modest benefits to be gained are not such as to offset the risk of significant side effects; subsequently it focuses, in particular, on the profiles of the bioethical debate regarding the use of neurostimulators by healthy subjects. On the basis of the available data on the scientific and empirical level, the Committee finally expresses several bioethical considerations, evaluations and recommendations.

The Committee does not consider unlawful, in general terms, a wise and properly regulated use of cognitive enhancers which are safer and more effective than those currently available, emphasising at the same time that many bioethical and policy issues should also be discussed and addressed. The NBC calls for new research in the neurobiological and neuropharmacological field, it reiterates the bioethical principles of experimentation (proportionality of benefit/risk, informed consent, approval of the relevant ethics committee) as regards the experimental protocols enlisting healthy subjects, it reflects on the problems of health justice, recommending that adequate information on the risks to society of such drugs and hopes for the startup of a more general public debate on the issues of *cognitive enhancement*. The Committee also points out that cognitive function can be improved in a more long-term way through study, continuous stimulation of interests, a rich social life and relationships, healthy lifestyle (nutrition, physical activity) and highlights how exaggerated expectations regarding the enhancing effects of

pharmacological neurostimulators derive from a reductive view of human intelligence.

The working group was coordinated by Profs. Vittorio Possenti and Monica Toraldo di Francia, the text was drawn up by Prof. Monica Toraldo di Francia. Written contributions were made by Profs. Antonio Da Re, Silvio Garattini, Laura Palazzani, Vittorio Possenti, Giancarlo Umani Ronchi and Grazia Zuffa. Profs. Salvatore Amato, Adriano Bompiani, Stefano Canestrari, Francesco D'Agostino, Lorenzo d'Avack, Carlo Flamigni, Marianna Gensabella, Laura Guidoni, Assunta Morresi, Demetrio Neri, Andrea Nicolussi contributed to the discussion of the text within the working group. The text makes use of the scientific contribution of Prof. Silvio Garattini, consulted during the plenary session.

The document was approved by majority vote. Profs. Luisella Battaglia, Adriano Bompiani, Bruno Dallapiccola, Lorenzo d'Avack, Riccardo Di Segni, Silvio Garattini, Marianna Gensabella, Laura Guidoni, Assunta Morresi, Andrea Nicolussi, Laura Palazzani, Vittorio Possenti, Monica Toraldo di Francia, Giancarlo Umani Ronchi, Grazia Zuffa gave a favourable opinion. Prof. Cinzia Caporale abstained from voting. Profs. Salvatore Amato, Stefano Canestrari, Francesco D'Agostino, Antonio Da Re, Maria Luisa Di Pietro, Demetrio Neri and Lucetta Scaraffia, absent from the meeting, subsequently adhered to the document.

The President
Prof. Francesco Paolo Casavola

Introduction

Following the document on *Neuroscience and human experimentation: bioethical problems* (17 December 2010), the NBC continues in the examination of issues relating to so-called ‘applied neuroethics’ by proposing some reflections on the theme of so-called cognitive ‘*enhancement*’ of a pharmacological kind and on the bioethical questions which it raises.

As is known in the last twenty years the theme of ‘*enhancement*’ - a conceptually ambiguous term, which will be used here in the restricted acceptance of *intentional use of knowledge and technologies for biomedical interventions on the human body in order to modify, in an ameliorative and/or potentiating way, its normal functioning*²⁹ - has been the focus of intense debate among philosophers, bioethicists and scientists of different orientations. This debate was stimulated initially by the encounter of genetic engineering and reproductive medicine and subsequently, subjection to the attention of so-called converging technologies (*Converging Technologies: Nano-Bio-Info-Cogno*), interweaving with the themes of bionic man the transhuman and posthuman, there has developed especially in view of possible future scenarios prefiguring an anthropological ‘revolution’ large enough to redesign human identity and the same mechanisms of evolution of the species.

We would like to start by saying, in order to avoid misunderstanding and confusion, that when it comes to the *enhancement* of human abilities, physical and/or mental, through biomedical technology we must keep in mind at least three fundamental distinctions:

- the first between enhancement of capabilities or existing functions/creation of new organic and mental features (e.g. the ability to read the minds of others, to withstand very high temperatures or vice versa, and the like);
- the second between enhancement of capabilities or transmissible functions (e.g. those possibly obtainable by means of germ cell intervention)/non-transmissible to descendants;
- the third between enhancement of human capabilities remaining within statistical normality (e.g. aimed at improving the performance of those who are ‘naturally’ disadvantaged compared with the average)/enhancement

²⁹ The restricted acceptance is indeed the one which today raises the greatest bioethical problems.

which strives to raise above ‘normal’ the performance of specific individuals or the general level of the population³⁰.

As is easily intuitable, cognitive enhancement techniques involve complex bioethical, anthropological and social issues which drive us to further refine analysis, avoiding hasty acceptance or rejection. In this document, however, the NBC does not deal with future scenarios of humanity being radically transformed by technology, nor, as regards “cognitive function”, the possibility still only hinted at, of using new genetic technologies or micro-electro mechanical enhancement (genetic engineering, brain computer interface, intracranial magnetic stimulation). The field of interest is limited to consideration of already existing scenarios, despite their different geographical diffusion, revealing the third of the distinctions mentioned, more specifically, here we take into account so-called pharmacological ‘neurocognitive enhancement’ - which in fact concerns, at least for now, only modest improvements possible in some specific and limited mental performance - which poses more concrete ethical questions, which need to be considered also with a view to highlighting the different profiles and stimulate a more informed public debate on the matter.

In the first part of the document it was considered appropriate, at the outset, to return to the controversial issue of the distinction between ‘normal’/‘pathological’ to highlight how it assumes an even more problematic nature in the sphere of neuropsychology, where the boundary between therapeutic/ameliorative becomes especially difficult to trace. Following on we deal with the ‘state of the art’, emphasising how pharmacological enhancement of ‘cognitive abilities’ is, in fact, currently limited to use of ‘*off label*’ medicines, developed especially for the treatment of psychiatric and neurological syndromes or diseases, by healthy individuals. The second part discusses the developments of bioethical debate around this issue, starting

³⁰ Cf. A. Buchanan, *Cognitive enhancement and education*, in “Theory and Research in Education”, 2011, v.9, 2, pp. 145-162. However, in other contexts, and always with reference to new technologies, it is possible to use a criterion of distinction, that is less analytical, such as the +one contrasting “improvement-optimisation” with real “enhancement” including in this “last category only those interventions that drive bio-physical capacity above the typical level of the species and beyond the statistically normal margins of functionality for individuals. Cf. *NBC Human rights, medical ethics and enhancement technologies in the military*, 13 March 2013.

from the publishing in “Nature”³¹ (2008) of an article, written by a group of scholars from various disciplines in favour of a responsible and controlled use of drugs for cognitive enhancement (henceforth PCE) if aimed at improving memory performance and learning in the scholastic-academic sphere. Reference to the developments of this debate will allow both to clarify, on the basis of the most recent empirical data, some of the misunderstandings that have made the discussion conceptually unsatisfactory, as well as permitting to draw distinctions concerning the underlying reasons for the consumption of non-medical ‘neurostimulators’, helpful to the more precise delineation of the issue in question and the problems it raises. The third part is devoted to bioethical evaluations and recommendations and distinguishes what is currently under discussion from the problems which may arise, in relation to this specific field, in the relatively near future.

1. The controversial boundary between therapeutic/ameliorative

Not being able, in this opinion, to enter into the merits of a dispute that has a long history and which pertains to the philosophy and epistemology of medicine, one can mention here that - while the fundamental opposition between ‘naturalists’ and ‘normativists’³² remains - today it is generally given that the line of demarcation between therapeutic-reparative/*enhancement* of functions and abilities can, at times, be faint and presupposes, however, a prior agreement regarding what is ‘normal’/‘abnormal’. In this regard, for example, even the document of the European Group on Ethics in Science and New Technologies (EGE), *Ethical aspects of ICT implants in the human*

³¹ H. Greely, B. Sahakian, J. Harris, R. C. Kessler, M. Gazzaniga, P. Campbell & M. J. Farah, *Towards responsible use of cognitive-enhancing drugs by the healthy*, in “Nature”, 2008, v. 456, n. 7223, pp.702-705.

³² ‘Naturalists’ think that we can give an objective scientific description that is value-free, of the distinction using statistical methods: the existence or absence of a deviation from the norms regulating the physiological functions typical of human organisms constitutes a universalisable criterion of distinction. ‘Normativists’ by contrast, consider that what is classed, in different eras and societies as ‘disease’ is always the result of a particular social context and cultural values that inform them, insisting on the aspects of social construction inherent to the definition of ‘health’ and ‘disease’, they believe that the two concepts are always permeated by value judgments determined historically and culturally. Cf. A. Pagnini (a.c.), *Filosofia della medicina. Epistemologia, ontologia, etica, diritto*, Carocci, 2010 (in particular: *Salute e malattia*, by Giovanni Federspil, Pierdaniele Giarretta, Nadia Oprandi).

body, cites as an exemplary ‘case’ which challenges the concept of the existence of a general standard of human capabilities - functions, the case of cochlear implants for deaf children, the particular concept of ‘normality’ that underlies the promotion of therapeutic purposes of such implants has, in fact, been challenged by the same deaf community that refuses to consider their condition as being deficient³³.

This issue becomes even more problematic when it is then faced in the relevant area of neuropsychology, where the boundary between therapeutic/ameliorative becomes particularly difficult to determine for several reasons, which it seems appropriate to mention briefly.

a. The first reason may be identified in the process of progressive medicalisation that, since the nineteenth century, has affected the emotional sphere. Those which were once considered as normal emotional reactions of living beings to the circumstances of life (bereavement, frustration, stress) have been gradually converted into pathological states, legitimising, in this sense, their medicalisation and the increasingly widespread use of the medical-psychiatric prescription of psychotropic drugs³⁴. The moment these emotional reactions are medicalised and classified in psychiatric language (depression, affective disorder, etc.) and treated pharmacologically, it so happens that people are more likely to seek medical attention to be helped to overcome with pharmacological assistance any state perceived as psychological distress. In this way, it becomes much more difficult to distinguish between those who take these drugs to restore a compromised mental balance and order to lead a ‘normal’ life and those who possibly make use of

³³ *Ethical aspects of ICT implants in the human body*, Opinion presented to the Commission by the European Group on Ethics, Brussels, 17 March 2005.

³⁴ B. Fantini, *An historical sketch of changing vocabularies of emotions*, Humana.Mente - Issue 9, 2009. On the trend toward medicalisation of life events and emotions, cf. also the report of the Canadian Commission on the Ethics of Science and Technology (CEST), *Psychotropic Drugs and Expanded Uses: An Ethical Perspective*, 2009. The document of the Canadian Commission is one of the few official documents - addressed to public authorities and professional groups working within health care, as well as the pharmaceutical industry - which makes a broad examination of the various aspects related to the expanded use of psychotropic drugs in the population and, in particular, to their non-medical use (especially prevalent in Canada and Quebec), and then goes on to conclude with a series of recommendations directed to all the parties involved.

http://www.ethique.gouv.qc.ca/INDEX.PHP?OPTION=COM_DOCMAN&ITEMID=22&LANG=FR%20PUBLICATIONS).

them to ‘improve’, or optimise their psychological well-being and performance in the sphere of education and work. In addition, medicalisation, by focusing on the biological aspect of distress tends to underestimate, if not disregard, the social causes and family/relationship linked causes which can be the very origin of the malaise.

It should also be kept in mind, when considering this aspect, that the classifications of syndromes and psychiatric disorders are still, in large part, merely based on symptomatology, without there being a knowledge of the possible biological roots of the disorder; an example being, the inclusion among psychiatric disorders of the new syndrome of attention deficit and hyperactivity³⁵ (ADHD: Attention Deficit Hyperactivity Disorder), which has aroused much controversy over the years and to which we shall return later.

b. A second reason lies in the possibility of making use, in order to justify the prescription and/or taking of medication to improve mood (mood enhancers) as well as cognitive performance, of the broad definition of health proposed by the World Health Organisation (the WHO, in its charter defines the concept of health as ‘*a state of complete physical, mental and social well-being*’). Such a definition inhibits the ability to make a clear distinction between disease and mental suffering, with all the effects, not only positive, resulting from an interpretation that emphasises the subjective dimension of suffering.

c. A third reason is that, even for the reasons mentioned, it is increasingly difficult to distinguish between treatment of affective disorders and mood, on the one hand, and cognitive *enhancement* on the other, since their relationship can prove to be circular: biomedical intervention that improves the state of mind may have positive effects on cognitive function, calming anxiety and strengthening motivation, similarly, an improvement of certain mental performance may have positive effects on the levels of mood and self-esteem.

³⁵ Attention Deficit Hyperactivity Disorder is a neuropsychological developmental disorder in children and teenagers, characterised, according to the criteria of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-III, DSM-III-R, DSM-IV), by inattention and impulsivity and/or hyperactivity all of these symptoms, which are not caused by cognitive impairment (mental retardation), but by objective difficulties in self-control and the ability to plan, are persistent in all contexts and situations of life of the child resulting in significant limitation of daily activities.

It is also based on these findings that some bioethicists have questioned not only the possibility of drawing, in different circumstances, a convincing distinction between therapeutic/ameliorative, but also the value of this distinction as a criterion for making judgments on the lawfulness/unlawfulness of the different practices made possible, or even just thinkable, by biotechnological development³⁶. In other words, equivalence between what is therapeutic and allowed, ameliorative-potentiating and not allowed, does not seem to be convincing and therefore of help as regards bioethical assessment.

2. Pharmacological “enhancement” of cognitive abilities: current issues and prospects

Returning to the theme of increasing individual cognitive abilities, there is a distinction, preceding all others, and should not be forgotten: that is between the ‘conventional’, ‘classic’ methods, for improvement - which are culturally accepted and that, in most cases, have been practiced for thousands of years: education, mental exercise, mnemonic techniques, and more recently use of electronic technologies etc... - and methods that can be defined as ‘non-conventional’ and still at the experimental stage, although at different stages of development, such as genetic engineering, neural implants, the deliberate creation of nootropics (from the Greek *noos*, mind, and *tropein*, monitor) etc.³⁷. As mentioned, it is with regard to the second that complex philosophical, anthropological, ethical and social problems have been raised, within the field of neuroscience. However, also included, as part of the second, is the more modest practice of cerebral stimulation through drugs.

³⁶ Of this opinion are some of the most famous protagonists of bioethical debate, for that matter, positioned on opposite sides, as, e.g. L. Kass, *Report of the President’s Council on Bioethics, Beyond Therapy. Biotechnology and the Pursuit of Happiness* and Dana Press, New York 2003 and N. Bostrom & A. Sandberg, *Cognitive enhancement: Methods, ethics, regulatory challenges*, in “Science & Engineering Ethics”, 2009, 15, 3, pp. 311-41. As noted by Kass, the ethically pertinent questions not so much about “whether or not a certain bio-medical practice is or is not aimed at care or enhancement, but rather those who ask themselves “*what are the good/bad uses of bio-technical power?*”, “*what makes utilization [of this power] good or at least acceptable?*”.

³⁷ Cf. N. Bostrom, A. Sandberg, *Cognitive enhancement* cit; S.M. Outram, *Ethical Considerations in the Framing of the Cognitive Enhancement Debate*, in “Neuroethics”, 2011, 5, Issue 2, pp.173-184.

The use of substances of various kinds (caffeine, nicotine, amphetamines etc...) to improve resistance to fatigue and intellectual performance has, as is known, a long history; the ‘novelty’ today is, rather, in the availability of more sophisticated pharmacopeia, developed for the treatment of psychiatric and neurological syndromes and diseases (Alzheimer’s, Parkinson’s, dementia syndrome, attention deficit and hyperactivity, narcolepsy, autism, etc.) whose use by ‘healthy’ individuals would seem to increase to some extent - albeit with conflicting results -short-term memory³⁸, the capacity for concentration and learning, cognitive control (which represent, it should be pointed out, only a few aspects of our mental processes)³⁹. In the last decade for this category of ‘neuroenhancers’, or ‘nootropics’, multiple labels have been coined, depending on an implicit positive/negative judgement on their non-medical use, as well as the intention to suggest analogies with other types of interventions on the body regarded as lawful/unlawful: *smart drugs*, lifestyle drugs (substances intended to alter lifestyle), *viagra for the brain*, cosmetic neurology, brain doping, etc.⁴⁰.

³⁸ Cf. M.J. Farah, J. Illes, R. Cook-Deegan, H. Gardner, E. Kandel, P. King, E. Parens, B. Sahakian & P.R. Wolpe, *Neurocognitive enhancement: what can we do and what should we do?*, in “Nature Reviews Neuroscience”, 2004, 5, Issue 5, pp. 421-425. The pursuit of control over the mechanisms of memory, however, is not just about the search for substances that can help to increase memory in the short and long term, but also that of agents that may prevent the consolidation of undesirable memories in the case of traumatic events. The use of drugs that can block unpleasant memories by those not the victim of trauma would be another way of alteration of the neural basis of memory in order to improve its normal functioning. On this last aspect and on the unilateralism of this approach to the conception of the functioning of ‘memory’ cf. N. Levy, *Changing One’s Mind. The Ethics of Memory Erasure in Eternal Sunshine of the Spotless Mind*, in “S & F”, 2011, n.5, online magazine: www.scienzaefilosofia.it.

³⁹ Needless to say, at least as regards the media reports of the debate on this type of cognitive potentiator, a reductive view of human intelligence tends to prevail, its being represented as a set of separate functions-performances, each of which can be acted on autonomously and effectively with a pill, without taking into account the environmental, emotional, and relational influences, affecting them.

⁴⁰ Cf. For example. J. Harris, *Chemical Cognitive Enhancement: Is it Unfair, Unjust, Discriminatory, or Cheating for Healthy Adults to Use Smart Drugs?*, in “Oxford Handbook of Neuroethics”, J. Illes, B.J. Sahakian (eds), Oxford Univ. Press, 2011; R. Langreth, *Viagra for the Brain*, in “Forbes”, 4 February 2002; *I doping della mente*, in “La Repubblica Salute”, 12/02/2009, p. 8; A. Chatterjee, *Cosmetic neurology - The controversy over enhancing movement, mentation, and mood*, in “Neurology”, 2004, 63, pp. 968-974; A. Chatterje, *The promise and predicament of cosmetic neurology*, in “Journal of Medical Ethics”, 2006, 32, pp. 110-13. Chatterjee, e.g., while highlighting the ethical and social issues currently causing concerns and uncertainties, there are no doubts that ‘cosmetic neurology’ will become in the near future, as acceptable as aesthetic surgery.

Among the molecules in question, whose continuative consumption seems to be especially prevalent among the students of Colleges and Universities in the United States and Canada, there are e.g. Ampakines⁴¹, which promise to enhance brain activity in memory and attention disorders, and others put on the market for the treatment of ADHD, such as methylphenidate⁴², or for the treatment of narcolepsy and sleep apnea, such as modafinil, a substance that, by acting on sleep-wake mechanisms, enables 'healthy' individuals to stay awake for many more hours than normal in terms lucidity and concentration⁴³.

According to the data found in the English literature concerned with the phenomenon of the consumption of PCE, the estimate, regarding North American Colleges and Universities, is approximately 7% - 8% of students, with peaks up to 25% or even 37%, but also among teachers, professionals and managers, the phenomenon seems to be in expansion. It is not surprising then that this literature tends to present the university campus as a kind of laboratory for nootropic testing, where every day young students carry out experiments on their brains using substances to improve their scholastic

⁴¹ The Ampakines are substances that interact with the AMPA receptor, potentiating the activity of glutamate, a neurotransmitter involved in learning processes and codification of memories.

⁴² The molecule that is effective in the treatment of ADHD is methylphenidate that is basically an amphetamine. In recent years the controversy about administering to children and adolescents diagnosed as suffering from ADHD drugs based on methylphenidate (marketed with the names of Ritalin, Adderall etc). has been fierce and criticism has been directed so much to the increasing number of these diagnosis, not substantiated by reliable tests, with regard to the side effects, even very serious ones, of the drugs themselves - the unspoken effects by the great pharmaceutical companies that market them making huge profits - and not least to the addiction that they can create. In Italy Ritalin was registered by AIFA in 2007; to avoid its being used unjustifiably there was established at the same time - at the Department of Medicine of the National Institute of Health - the National Registry for ADHD, whose protocols are described in the ISTISAN Report 09/20. The registry is the instrument to prevent misuse of the medication, by providing support for the diagnosis - which can only be made at an authorised Centre for mental health and neuropsychiatry afferent to the registry - as well as the choice of treatment, which may not be pharmacological. This means that medication is under control and children who are subjected to therapy (today around 1700) are about ten times fewer than those of other countries. Adderall, instead, has not yet been registered in Italy.

⁴³ Modafinil is used to treat excessive daytime sleepiness in patients with narcolepsy, a neurological disorder originating from an alteration of the central nervous system mechanisms that regulate our sleep-wake rhythms. Its precise operational mechanisms are not yet fully known although - as explained by Cristina Colombo who is in charge of the Centre for Mood Disorders at the Hospital San Raffaele Turro - "*We know that it stimulates the production of dopamine, substances responsible for the acceleration of the heartbeat and a rise in blood pressure, setting in motion a series of functions such as concentration and alertness.*"

performance and feel more competitive with less stress. As for ‘where’ to obtain PCE, according to a recent study, 52% of those using them make use of a medical prescription (even faking ADHD symptoms), 14% turn to compliant pharmacies, while the remaining 34% buy them through the Internet, where there is an abundance of so-called cyberpharmacies, or on the black market on campuses, regardless of the additional risk that this may entail⁴⁴.

However, one should add that the neuroenhancers currently in circulation all have very limited effectiveness, but raise quite a few problems with regard to their ‘safety’, however, since pharmaceutical companies are investing a lot of money and time in the development of molecules aimed at the treatment of cognitive decline (both physiological and pathological), many people think that it will soon be joined by a safer and more effective pharmacopoeia⁴⁵. It is said that there is strong request from an aging population which cannot bear to lose its memory, parents determined to stimulate their children by whatever means, students and professors busy competing with each other in the academic arena, professionals stressed by an unsustainable pace of work. There are those who believe therefore that in the very

non-medical use of modafinil may be dangerous to health as it tends to be misused, by exceeding the recommended doses: By continuing to stimulate the production of dopamine, for example, increases the burden on the heart and increases the risk of heart attack. In addition, sleep is a necessary function to the brain and psyche, and it is “essential for the reorganisation of cognitive functions such as memory and learning”. Since 2000, Modafinil has become available in Italy, but its use restricted to two criteria: the first is that the drug can only be prescribed by specialists for narcolepsy (by neurologists and pneumologists when it comes to patients suffering from obstructive sleep apnea, for which the drug has proved an effective aid), the second criterion is linked to the accurate estimation of epidemiological data in order to understand the level consistent with appropriate use. (<http://d.repubblica.it/dmemory/2007/03/10/attualita/attualita/120sci539120.html>). In a recent intervention Nora Volkow, director of the National Institute on Drug Abuse (U.S.), recalled that in the UK, unlike the U.S., the use of neurostimulants by the military was banned after the discovery that they could lead to paranoid disorders: cf. S. Hyman, N. Volkow, D. Nutt, *Pharmacological cognitive enhancement in healthy people: Potential and Concerns*, in “Neuropharmacology”, 2013, 64, pp. 8-12. As for the more general *off-label* use of these substances in the military field, refer to NBC, *Human Rights, Medical Ethics and enhancement technologies in the military*, 13 March 2013.

⁴⁴ S.M. Outram, *Ethical consideration in the framing... cit.*

⁴⁵ But there are also scientists, engaged in this field of research who consider such a forecast too optimistic, e.g., Gary Stix, one of the most well-known collaborators of ‘Scientific American’, believes that it is highly unlikely - given our little knowledge of various aspects of neuropsychopharmacology - that in the near future we will be able to develop a drug, that does not produce serious health risks, capable of improving memory, attention and the speed of learning.

<http://blogs.scientificamerican.com/observations/2011/12/07/are-we-as-smart-or-dumb-as-we-can-get>.

near future neuroscience will make significant progress as to the understanding of our complex brain mechanisms and that more valid cognitive enhancers than those available today will be developed: some people will use them as therapy, others because their requirement is ‘borderline’ and others simply to have an advantage in competition⁴⁶. But there are also those who sustain - based on a highly biologicistic conception of mental functioning - that the democratic values underlying our public education systems militate in favour of the institutionalisation of pharmacological cognitive enhancement in the education sector, and more generally in the educational process, if they came to develop PCE that in addition to being safer, were also able to ensure the better functioning of normal cognitive processes. According to proponents of this conception⁴⁷ (widely criticised from many sides) the institutionalisation of cognitive enhancement, under the conditions described above instead of inciting new inequalities, could mitigate existing ones and, at the same time, help to correct biochemically those cognitive defects that come under human ‘normality’ and impede optimal functioning of our mental abilities⁴⁸.

⁴⁶ M. Talbot, *Brain Gain*, New Yorker, April 27 2009. Italian translation: *Con un poco di pillole il cervello va su e diventiamo più efficienti, lucidi, creativi, wow! o è solo doping cerebrale?*, <http://mag.wired.it/rivista/storie/con-un-poco-di-pillole-il-cervello-va-su.html>.

⁴⁷ Cf. A. Buchanan, *Cognitive enhancement and education*, cit. It should be noted that in the ranks of so-called ‘technophiles’, there are also those who believe that cognitive “enhancement” is not desirable, because it is too dangerous for the survival of the human race, unless it is accompanied by a corresponding moral “enhancement of human beings, obtainable by the development of new biomedical and genetic technologies”: cf. I. Persson & J. Savulescu, *The Perils of Cognitive Enhancement and the Urgent Imperative to Enhance the Moral Character of Humanity*, in “Journal of Applied Philosophy”, 2008, 25, (3), pp. 162-177.

⁴⁸ According to Allen Buchanan the institutionalisation not only has a positive impact on individual development (the *individual’s flourishing*) and social well-being as a whole, but would also contribute to overcoming the stigma against those who are diagnosed as suffering from specific learning disorders, such as, for example, ADHD. Next, as regards “normal” cognitive defects of the species he does not ignore that they may be, or have been functional to our relationship with the outside world and with others, nevertheless, he believes that, in the near future, they may prove harmful faced with the challenges that will arise. In his view, therefore, the objective should be not only to improve the condition of those at the lowest end during the ‘natural’ distribution of mental abilities, but it should also include the improvement of normal cognitive functions of the average person and increment our ability to absorb and integrate information. In contrast, the advantages of functioning by means of not perfectly logical mental patterns have been the subject of numerous studies (cf. e.g. E. Boncinelli, *Il cervello la mente e l’anima. Le straordinarie scoperte sull’intelligenza umana*, Mondadori, 1999, chapter VII). More recently,

3. Profiles of the debate on the use of neuroenhancing drugs by the healthy

In the context of bioethical debate on pharmacological cognitive *enhancement* - firstly in the Anglo-American area and later also in other countries, including Italy - there was a defining moment with the publication in “Nature” of a deliberately provocative article written by many people together and entitled *Towards responsible use of cognitive-enhancing drugs by the healthy*⁴⁹. But in previous years several essays on neurocognitive enhancement had come out which had taken into account, above all, the pharmacological phenomenon and outlining the subsequent bioethical debate on the subject⁵⁰. All authors started with the assumption that the phenomenon of the non-intermittent consumption of PCE was a phenomenon in constant expansion - a “fact of life” already for many people - which, like it or not, had to be acknowledged.

In the article in “Nature” Henry Greely and the other signatories were, on the whole, in favour of a controlled and responsible consumption of neurostimulants designed to improve concentration, speed of response, short-term memory, etc. Assuming that the use of these neuroenhancers by the “healthy” (i.e. those not in need of the drug for therapeutic purposes) is largely dictated by the desire to have higher marks and to improve one’s capacity for study and learning, they wondered whether it would be better to make consumption lawful rather than leaving the demand to the black market, that is to say, illegal and uncontrollable. It was also pointed out how the strong social pressure that drove people to seek to raise the level

Gary Stix has insisted on the paradoxical and undesirable consequences that may occur with the non-medical use of stimulants to increase certain cognitive performances such as, for example, the ability to focus attention: to be mentally fixed on a single task may in fact be of hindrance rather than of help to the flexibility of thought needed to address a very significant intellectual challenge. Furthermore, according to Stix, “*the complex mix of chemical signals, enzymes and proteins that collaborate to form a memory creates a self-regulating balance that resists tinkering unless disrupted by disease*”:

<http://blogs.scientificamerican.com/observations/2011/12/07/are-we-as-smart-or-dumb-as-we-can-get>.

⁴⁹ H. Greely, B. Sahakian, J. Harris, R.C. Kessler, M. Gazzaniga, P. Campbell & M.J. Farah, *Towards responsible use of cognitive-enhancing drugs by the healthy* cit.

⁵⁰ Among them: A. Chatterjee, *Cosmetic neurology...* cit. And by the same Author, considered one of the most knowledgeable scholars of the subject, *The promise and predicament of cosmetic neurology* cit; Martha J. Farah *et al.*, *Neurocognitive enhancement: what can we do and what should we do?* cit; B. Sahakian and S. Morein-Zamir, *Professor’s Little Helper*, in “Nature”, 2007, pp. 1157-1159.

of their performance in education and work could trigger some real mental illness (performance and competition anxiety), which would have been better prevented, even allowing the use of pharmacological aids of the kind mentioned⁵¹.

The discussion opened by “Nature” was then further enhanced thanks to a series of contributions that focused attention, especially on two ethically important issues: the relationship between the expected benefits and risks to health and the possibility that the various access opportunities to these substances generate socially discriminatory situations. What however should be emphasised here is that the same approach to the problem, as outlined by Greely and his companions, has the object of criticism of some recent publications⁵², particularly with regard to two central aspects of their premise: the first concerns the distinction between subjects considered as healthy according to a standard of statistical normality/individuals with cognitive difficulties, and the second concerns instead the reasons underlying the consumption of neuroenhancers by the student population.

For the first aspect, new empirical studies have highlighted how some of the so-called “healthy individuals” included in the estimates of consumers of PCE for scholastic- academic purposes, in fact, show symptoms very similar to those identified with the syndrome of attention deficit and hyperactivity disorder (ADHD), or at least revelatory of specific undiagnosed cognitive difficulties. In these cases, the use of the substances in question could be regarded as a kind of “self-treatment” and not as

⁵¹ In the wake of these interventions “Nature Network” has also carried out, in April 2008, an informal online survey, which asked readers-scientists if they had tried to improve “attention, concentration or memory” through the use of drugs such as Ritalin (methylphenidate), or Provigil (generic name: modafinil). Responses were prompt: a reader in five responded affirmatively. The majority of the 1,400 respondents - of 60 different nationalities - also claimed to be in favour of adults being allowed to decide for themselves whether to take nootropics or not. 69% considered any side effects to be an acceptable risk, while a third of the readers admitted they would feel impelled to give their children these so-called smart drugs if they come to know that this practice was being adopted by other parents.

⁵² See in part S.M. Outram, *Ethical considerations in the framing...* cit. and the extensive bibliography that accompanies this essay; D. Repantis, P. Schlattmann, O. Laisney and I. Heuser, *Modafinil and methylphenidate for neuroenhancement in healthy individuals: a systematic review*, in “Pharmacol. Res”, 2010, 62, pp. 187-206.

⁵³ S.M. Outram, *Ethical considerations in the framing...* cit. On the difficulty of establishing a reference standard for cognitive functions, given the diversity of human beings, cf. *Commission on the*

the search for a real enhancement of ‘normal’ cognitive abilities⁵³ (‘normal’ is used here as a statistical concept in correspondence to a standard). If this is true, it follows that either we review the belief that the non-medical use of stimulants for scholastic-academic reasons is necessarily a form of “*cognitive enhancement*”, or we acknowledge the difficulty of separating the self-treatment of cognitive disorders from *enhancement*, with the consequence of making even more difficult and confusing the abstract distinction between enhancement and therapy. The condition of ambiguity, in this case (as in others), is in fact accentuated by the fact that the same molecule is associated with both the concept of ‘therapy’ and that of ‘enhancement’.

With regard to the second aspect, many parties have highlighted the need to collect a larger number of data on the frequency of consumption and the reasons underlying the use of nootropics, also to avoid the risk of an overestimation of the current phenomenon of the search for intellectual enhancement, confusing what, in actual fact, are “recreational aims” with the desire to improve one’s cognitive performance⁵⁴.

The most recent research, taken as a whole, allows for some general observations to be made, that are useful to set in a more analytically accurate manner related bioethical assessments.

a) A first observation concerns the difficulty of gathering information about epidemiologically significant effects on ‘healthy’ individuals - in terms of the effectiveness and safety - of various neurostimulants.

This difficulty is due to the fact that the data reported in the studies in question (still very little) vary considerably for two reasons: because of the

Ethics of Science and Technology (CEST) Canada, *Psychotropic Drugs and Expanded Uses: An Ethical Perspective*, cit; in this regard, the Commission notes that in reality any definition of “normality” cannot but be complex, and of a subjective and evolutionary nature.

⁵⁴ It is estimated, very approximately, that in the list of motives in first place there is the desire to improve attention and in second place “recreational aims”, the “enjoyment of” free time (but the two motives are often combined), followed by the desire to acquire a different style of studying, to get higher marks and the need to reduce hyperactivity. However, for an accurate estimate of the true motives, the data available is still conflicting and insufficient: cf. C.A. Ragan, I. Bard, I. Singh, *What should we do about student use of cognitive enhancers? An analysis of current evidence*, in “Neuropharmacology”, 2013, vol. 64 (*Cognitive Enhancers: molecules, mechanisms and minds 22nd Neuropharmacology Conference*), pp. 588-595.

differences in the methods applied in the experimental protocols⁵⁵; because, dealing with illegal practices, the collection of data on their diffusion is anything but simple. There is, indeed, an understandable resistance to come out into the open and, also, those who let themselves be interviewed, by admitting to make use of these drugs, are often brought, more or less consciously, to accentuate the benefits and minimise any adverse effects. More specifically, with regard to the effectiveness of these neuroenhancers in general, it turns out to be very low and very variable, according to the most recent reviews of experimental studies.

Resulting from this is the general recognition by the scientific community, of the need for better coordination of research, with standardisation of methodologies, together with the need to ‘increase knowledge’ of the delicate balance of the brain with which it is interfering and the complex mechanisms that modulate the diversity of individual responses when taking nootropics, of one kind or another (not coincidentally a substantial part of neuropharmacological and neurobiological research is currently directed precisely to the identification of the factors, biological or otherwise, which may affect this variability).

As regards, more particularly, the risks to health of PCE - whose long-term effects are, however, still almost unknown - it should be noted that even on this aspect there is no agreement, apart from the fact that their non-intermittent use can have very serious and/or long-term side effects and that there is a need to carry out further studies in this regard. You may however consider that the modest benefits possibly obtainable do not seem, at present, able to balance the risk of significant side effects for those who take them for non-medical purposes⁵⁶.

b) More importantly, from the perspective of cognitive neuroscience, is the aired possibility, supported by some empirical data, that these drugs

⁵⁵ With reference to both the different levels of difficulty of the tests to which recruited subjects in the research are subjected, as well as to the different methods of measuring the results. Cf. M. Husain and M. A. Mehta, *Cognitive enhancement by drugs in health and disease*, in “Trends Cogn. Sci.”, January 2011, 15(1), pp. 28-36.

⁵⁶ The problem of “safety” concerns, of course, all drugs, none of which is devoid of side effects, but tolerance to the possible risks cannot but be much lower when there is no necessity to treat a disease.

- taken by healthy persons and those who are not in good health - while improving individual aspects of cognitive functioning depress others. With regard to those 'healthy' individuals, some researchers that have long been dealing with the issue⁵⁷ have asked themselves whether neuroenhancers that heighten attention may not at the same time blunt creativity and/or other mental functions. In support of this prestigious studies in cognitive psychology are cited, which claim that there is an inversely proportional relationship between concentration and creativity.

c) Also pointed out is that there is now much evidence also in favour of the thesis by which the PCE available today (for the three mental domains of short-term memory, of attention-learning ability, cognitive control) work on average but in descending order, i.e. in an inversely proportional way to the so-called 'IQ' of those who use it⁵⁸.

d) Lastly, it must be emphasised that many of the considerations in the bioethical debate are still of a speculative nature and projected towards the future, as for now, there are no drugs available that demonstrate a favourable benefit-risk ratio. The effects of enhancement recorded at the moment are of little importance as they are limited to specific experimental situations that have little significance for the improvement of functions linked to the cognitive process⁵⁹.

4. Evaluations and recommendations

As we have seen, issues related to the use of PCE have been for some years the subject of a vivacious scientific, bioethical and biopolitical debate seeing English scholars in the front line. The issues raised by non-medical use of nootropics, intertwine with questions of great complexity, of a more philosophical-gnoseological nature which however do not come into or only indirectly fall within the context of this document, e.g. the question of de-

⁵⁷ M. Farah, C. Haimm, G. Sankoorikal, A. Chatterjee, *When we enhance cognition with adderall, do we sacrifice creativity? A preliminary study*, in "Psychopharmacology", 2009, 202, 1, pp. 541-547.

⁵⁸ Martha Farah hypothesises that this is due to the fact that people with naturally low levels of dopamine are those that can benefit more from an artificial boost.

⁵⁹ Cf. *Cognitive Enhancers: molecules, mechanisms and minds 22nd Neuropharmacology Conference: Cognitive Enhancers*, in "Neuropharmacology", 2013, v. 64, in part. *ivi* C.A. Ragan, I. Bard, I. Singh, *What should we do about student use of cognitive enhancers? An analysis of current evidence* cit.

termining the meaning and content of the notions of ‘knowledge’ and ‘cognitive’ - which are not reducible to a sum of individual performances - or the question of whether what is being ‘enhanced’ is the brain or the mind, which refers to the more general discussion on the relationship between mind and brain and their related themes and issues⁶⁰.

In short, at present it is difficult to make a univocal bioethical judgment about PCE which could be developed in the near or distant future, for the many reasons already mentioned: research still in its initial stages together with its remarkable acceleration that does not allow adequate moments for adjustment, the still partial knowledge of how PCE works and the complex brain mechanisms which they affect, etc. With the caution mentioned above - and with the realistic expectation that not even in years to come will there be a “magic” pill capable of improving our cognitive performance⁶¹ replacing the usual processes of education and training, study and learning - it can be assumed that in future a ‘wise’ and properly regulated use of cognitive enhancement of a pharmacological kind, is not, in principle, in itself morally reprehensible, once its effectiveness and its not being harmful has been ascertained. Its not being abstractly unlawful, however, does not eliminate the numerous problems regarding bioethics and policy - already explored in literature - that the possible development of safer and more effective PCE raises and which it is appropriate to mention here, these particularly include:

⁶⁰ Intertwined to this issue are the questions raised by Neil Levy on the limits of acceptability of practices that relate to the functioning of the mind and the problematic nature of the significance, for ethical judgment, of the distinction between the changes and enhancements concerning the manipulation of “external” mental resources (notebooks, lists, computer etc.) and those which apply to the manipulation of internal resources with interventions on brain mechanisms: N. Levy, *Neuroethics and the Extended Mind*, in J. Illes and B. Sahakian (eds), *The Oxford Handbook of Neuroethics* cit.; see also N. Levy, *Neuroethics and the Extended Mind* in J. Illes, B. Sahakian (eds.) *The Oxford Handbook of Neuroethics*, cit.; see also *Oxford Handbooks of Neuroethics* for a comprehensive and updated view of the themes central to the debate on the present and future of neuroscience and related gnoseological, ethical, legal and political issues (consciousness and intentionality, responsibility and determinism, mind and body, neurotechnologies aging and dementia, legislation and public policy, science, society, and international perspectives).

⁶¹ Cf. the call to scale down expectations by N. Volkow (Director of the National Institute on Drug Abuse - NIDA - at the National Institutes of Health), in S. Hyman, N. Volkow, D. Nutt, *Pharmacological cognitive enhancement in healthy people: Potential and Concerns*, cit.

1) coercion (direct and indirect) and freedom: discussion - in the hypothesis of legalisation - on the possibility that this practice could, even if it weren't compulsory nevertheless become coercive for the population in general or for specific categories (both in the public and private sector) in terms of the penalisation-marginalisation of those refusing to use it;

2) equality: also cause for concern is the possibility that, leaving the regulation of distribution to the free market, only wealthy people could, however, afford access to PCE that is effective and likely to be very expensive, resulting in further accentuation of the already existing 'natural' and social inequalities. This problem is the subject of animated discussion in the context of different models of *distributive justice* that have queried the criteria which is most suitable for a 'fair' allocation of resources for enhancement⁶²;

3) fairness and merit: moreover the question arises as to how one could ensure fairness in competition and the principle of merit should the liberalisation of PCE be accepted;

4) self-perception and perception of the social bond: with regard to this it has been pointed out that there is the risk that the spread of the use of PCE may favour a view of one's actions directed more to one's immediate performance rather than to one's commitment to self formation and that this is likely to affect self-perception and the sense of one's 'value' and, at the same time, accentuate the tendency to compete rather than to cooperate.

Having said this, with reference to the current state of empirical research, scientific knowledge, the pluralistic bioethical debate on the use of PCE and certain trends found within the individual and social context - but also warning that the picture is continuously complicated by the difficulty, repeatedly underlined, in establishing an unequivocal boundary between therapeutic purposes and enhancement purposes - the NBC makes the following general evaluations:

1) the issue of cognitive enhancement presents numerous innovative elements, which are still in need of adequate and continuous investigation;

⁶² There seems no doubt that the more ethically appropriate criterion is that of distribution according to need especially in the event of cognitive deficits and related "aids" that compensate for disadvantage and reconstitute some kind of equality of opportunity.

this aspect is further exacerbated by the general lack of empirical data and statistical results. The international debate on PCE has reached to date rather inhomogeneous results, given the general scarcity of empirical data and statistical results with respect to their possible effectiveness, their harmfulness, the methods of their use and distribution. Still almost nothing certain is known about the short-term and long-term effects and, on the phenomena of dependency that may be associated;

2) Therefore further research is important, in the field of neuroscience and brain functioning, directed at identifying more accurately and in detail effectiveness and side effects of these drugs on sick individuals, even in order to better determine whether possible use for enhancement purposes of a specific function does not lead to the (possible) decline or impoverishment - temporary or irreversible - of other functions⁶³ with possible irreversible damage and dependency. And it is, at the same time, hoped that there will be an increase in the pre-clinical research on the subject. As for the testing of these molecules on healthy subjects the same recommendations on ethical requirements apply as expressed in the previous opinion of the NBC *Neuroscience and human experimentation: bioethical problems*⁶⁴: benefit/risk ratio proportionate informed consent preceded by adequate counselling, utility of the research and approval by the appropriate ethics committee;

3) A delicate problem concerns the distribution and allocation of resources to the field of cognitive enhancement that may be at the expense of those intended to cure (therapy) and prevention (prophylaxis). On the other hand it is a fair assumption that much research aimed at enhancement will not be developed for a considerable time but rather research to fight debilitating and degenerative diseases or conditions, it cannot be

⁶³ On the state, still in its initial stages of research on the neural basis of highly complicated functions such as attention, memory, executive functions, etc.. cf. podcast brought by the 22nd Neuropharmacology Conference on Cognitive Enhancers, moderated by T. Insel, *Director, National Institute of Mental Health, NIH, USA*, with the participation of J. Krystal, M. Ehlers, *New Drugs Development for Cognitive Enhancement in Mental Health: Challenges and Opportunities*, 2012.

<http://www.journals.elsevier.com/neuropharmacology/podcast/free-podcast-on-new-drug-development/>.

⁶⁴ Opinion of the 17th of December 2010.

ruled out that, sooner or later, there will be research started aimed only at enhancement, with the correlative question of the moral acceptability of that choice. With regard to this, the NBC believes that with the scarcity of resources, which is generally the common situation public intervention to support research on enhancement would not be advisable, if it came at the expense of research and development plans dedicated to drugs for therapeutic purposes;

4) It should also be considered that cognitive function can be improved in a more lasting manner through instruction, education and continuous training, a rich social life and from relationships, from study, learning, continuous stimulation of interests, from healthy lifestyles (nutrition, physical activity). It is a path that clearly requires a lot of time, but (perhaps) it is more respectful of the opportunities for growth and development of personal and relational identity as well as of self-esteem and the feeling of 'self-fulfilment'. In addition, paradoxically, the positions of those who today say they are in favour of the liberalisation of PCE can be seen as a further attempt, with regard to the many already present, of medicalisation of everyday life and for quick and "easy" solutions, via the taking of a drug, to difficulties and problems which instead require more careful reflection as well as social and institutional management;

5) Similarly it should be emphasised that one of the factors underlying the impetus for the non-medical consumption of these "pills" is often a reductive vision, which identifies intelligence in a quantitative manner with the increase-expansion of notions-information, without considering that intelligence involves a qualitative dimension and needs a solid emotional "foundation" to be developed and exercised. The exaggerated expectations of *cognitive enhancers* may lead to a sort of 'drug-centeredness' attributing to chemistry a power to shape human beings far above reality;

6) Then one should question whether the absence of a pathological condition, diagnosed as far as possible clearly and definitely justifies the use of PCE notwithstanding risks and damage even if only probable and/or possible arising from the interference of these interventions with delicate and complex brain mechanisms. Here there emerges a profile of responsibility of each individual not only towards their own health but above all of the medical specialist who must ensure the appropriacy of the prescription and therefore prevent an "improper" non-therapeutic use of these

drugs⁶⁵. It is also desirable to find suitable methods to prevent the purchase of PCE via the Internet, which as a tool facilitates an uncontrolled spread and without a prescription, with inevitable negative consequences at the personal and social level;

7) But the questions raised by PCE do not only concern individuals and their self-determination: they intersect numerous problems with regard to social life, the sense of belonging of citizens and their relationship with others. Undoubtedly today the phenomenon of recourse to neuroenhancers, to improve one's performance in various fields, is stimulated by strong environmental pressures accentuating competitiveness, and the present climate of growing insecurity about the future, which also has the effect of eroding the non-formal adherence to the values of personal commitment, loyalty, *fairness*, solidarity etc. There emerges here the problem of possible *feedback* which, in turn this practice, if not properly regulated, could have in consolidating a mentality set on thinking of one's actions in terms of the immediate maximisation of productivity, of efficiency - even beyond one's capabilities - or competitive record. The bioethical problem does not concern only the harmfulness to health; it also calls into question the consideration of basic social-political values such as equal opportunities, fairness, and cooperation. This applies even more strongly - as mentioned above - if

⁶⁵ With regard to this see: *Letter to the Editor. Better evidence for safety and efficacy is needed before neurologists prescribe drugs for neuroenhancement to healthy people*, in "Neurocase: The Neural Basis of Cognition", 2012, v.18, Issue 3; and E. Racine, C. Forlini, *Disagreements with implications: diverging discourses on the ethics of non-medical use of methylphenidate for performance enhancement*, in "BMC Medical Ethics", 2009: <http://www.biomedcentral.com/1472-6939/10/9> which calls into question the guidelines expressed by the Ethics Law and Humanities Committee of the American Academy of Neurology, for the behaviour of neurologists in the face of a request, by healthy individuals, for drugs for the improvement of cognitive functions. Cf. D. Larriviere, M.A. Williams, M. Rizzo, R. J. Bonnie, On behalf of the AAN Ethics, Law and Humanities Committee, *Responding to requests from adult patients for neuroenhancements: Guidance of the Ethics, Law and Humanities Committee*, in "Neurology", 2009, 73, pp. 1406-1412. According to the Committee of the American Academy of Neurology, the prescription of substances of this type for 'neuroenhancement' is not - both in legal and moral terms - obligatory nor prohibited: the decision rests with the neurologist who has to take it within the doctor-patient relationship and respecting the criteria of informed consent. The criticisms raised by Eric Racine and Cynthia Forlini have shown that these guidelines do not consider adequately neither the social aspects of PCE or the particular responsibility of specialist doctors - whose purpose is the protection of the complex bio-psychological functions of the brain - and which, in addition, are based on a tacit acceptance of the safety and efficacy of the drugs in question.

one considers that in future safer and more effective nootropics could be developed. If free use of PCE was accepted, perhaps difficult to find and/or particularly expensive, this could give rise to other forms of undue advantage to the benefit of those who may have recourse to it, both in scholastic- academic and work contexts, accentuating existing inequalities and altering even more the sense of common citizenship and social solidarity;

8) Therefore the NBC does not consider - even in the presence of new safer and more effective molecules - the free market for pharmacological cognitive enhancement, managed only on the basis of the encounter between supply and demand, to be bioethically acceptable. There are areas that need to be protected from the intrusion of the market and trade, especially in a general situation in which for a long time now, the “mentality” that impels towards medicalisation, encouraging merchantilism, tends to invade areas of life traditionally managed according to a different logic. Similarly state intervention would not be acceptable, neither in the private context of work, led by the intention to favour the establishment of purported public interests nor private interests, i.e. orientated to paternalistically enhance their citizens, or its own officials or employees;

9) In conclusion, with regard to this, it is important to have a proper information and awareness on the part of public opinion regarding the expectations that the use of PCE can realistically meet and, even more, about the possible risks and damage to health, both mental and physical, that is associated. Special attention altogether must be dedicated to children, because of their particular vulnerability, the possible long-term effects (still not fully known) of this type of nootropic on a brain still in formation;

On the basis of these evaluations the NBC recommends:

1. that Italy should also intensify research into the cerebral sphere, taking account of the numerous international programs in progress;

2. that, at present, very severe constraints for the prescription of drugs with neuroenhancing effects be maintained and that these should always and only be prescribed by specialists in the sector with specific skills in neuropharmacology;

3. that public institutions should seek suitable methods for the implementation of a campaign for prevention- information, addressed to the medical sector, schools and families, which is not limited to illustrating the

harmful effects on health of these artificial aids and the highlighting of their limited effectiveness as cognitive enhancers, but it should also be directed to a better knowledge and critical consideration of the factors predisposing to their consumption by young people, in order to identify strategies to strengthen the individual, the environmental and cultural factors that may hinder the expansion of a black market;

4. that, pending further epidemiologically significant research into the short-and long-term effects of PCE (research concerning both intrinsic safety and the possible adverse effects on other mental functions, as well as social life as a whole), a public discussion on the more general issues of cognitive enhancement should be started, with the contribution of experts from the various fields involved, so as not to be unprepared if in the near future safer and more effective nootropics should become available.

Presidenza del Consiglio dei Ministri



BODY DONATION FOR SCIENTIFIC RESEARCH

19 April 2013

Presentation

The Opinion focuses the attention on a particular modality of donation or more specifically on the possibility to donate one's body to study and research activity, such as for example anatomy dissection lectures, aimed at the medical-surgical training of undergraduate and post-graduate students and the refresher courses for consultants. In outlining the ethical importance of donation, at the same time the NBC sets out to stress the ethical unacceptability of what is foreseen in Art. 32 of "Royal Decree Law" No. 1592 of 31 August 1933, which is still in force, that is the destination of the bodies of people who are unknown or without relatives and friends to teaching and research, insofar that no one claims their body for burial.

Body donation is inspired by a principle of solidarity towards others, carried out in the specific case by means of the fostering of study and research and indirectly the protection of health. It is absolutely essential that donation is the expression of a free and conscious decision by the subject. For this capitalized reason, the NBC considers that the principle of the donor's conscious and informed consent must be strictly respected and that the silence-assent mechanism may not be applied in any way whatsoever. Furthermore, the subject's decision cannot be subordinate to the consent or the non opposition of the relatives, even if it is hoped that the choice to donate is shared by the family and that it is suitably involved in the various phases, starting with the donor reaching their decision. Moreover, the role of the relatives can be important also in the carrying out of the donor's will; in this sense the appointment of a trustee could also be opportune, with the task of seeing that the donor's will is respected.

The working group was coordinated by Profs. Luisella Battaglia, Antonio Da Re, Giancarlo Umani Ronchi. The Opinion was drafted by Profs. Luisella Battaglia, Antonio Da Re, Lorenzo d'Avack and Giancarlo Umani Ronchi, who made use of, among others, significant contributions given by Stefano Canestrari and Andrea Nicolussi and the discussion group in which Salvatore Amato, Marianna Gensabella and Assuntina Morresi also took part. The final text, which takes into account all the observations arising even in the plenary sittings, was drafted by Prof. Antonio Da Re.

It must be remembered that on 16 April 2012 Hon. Eugenia Roccella, a Member of the Social Affairs Committee of the Chamber of Deputies, in reference to a number of bills still being debated, had presented the Presi-

dency of the NBC with a query on the issue, inviting it to express an ethical evaluation on it (see Attachment). Prof. Massimo Tabaton, of the Department of Internal Medicine of the University of Genoa, had urged the NBC to express an Opinion on the subject too.

In its identification of the most interesting subjects to be examined in the Opinion, the working group was able to make precious use of a document sent by the research group coordinated by Prof. Raffaele De Caro, responsible for the department of Human Anatomy at the University of Padua and dedicated to *The role of anatomy in modern medical training and body donation: the Paduan experience*. The drafters of the Opinion would like to thank Prof. De Caro and his collaborators for their contribution, and moreover Giulia Rigoni Savioli, from the Biblioteca Medica “Pinali” Antica of the University of Padua, for her precious help in the bibliographical research regarding paragraph 2 of the Opinion and its historical nature.

During the plenary sitting of 19 April 2013 the opinion was approved unanimously by those present, Profs. Salvatore Amato, Luisella Battaglia, Adriano Bompiani, Stefano Canestrari, Antonio Da Re, Riccardo Di Segni, Silvio Garattini, Marianna Gensabella, Laura Guidoni, Assunta Morresi, Demetrio Neri, Laura Palazzani, Vittorio Possenti, Monica Toraldo di Francia, Giancarlo Umani Ronchi. Profs. Cinzia Caporale, Bruno Dallapiccola, Lorenzo d’Avack, Andrea Nicolussi, Lucetta Scaraffia and Grazia Zuffa were not present at the voting but later gave their approval.

The President
Prof. Francesco Paolo Casavola

Premise

At present medical training can count on innovative methods and instruments, made possible by the considerable and constant evolution of surgery, especially in recent decades. Thanks to minimally invasive and robotic surgery it is possible to practise with video-trainers or simulators; once recorded and reproduced, the practical exercises make it possible to carefully examine the different phases of the methods used, any errors made, and the progress ascertained. Today surgical training can also make use of e-learning and multi-media methods, aimed at fostering active learning and possibly the participation of those operating in the very decision-making process.

Despite these new techniques, which nonetheless cannot be applied to all cases, international scientific literature agrees that any direct practice on the dead body cannot be substituted and that anatomy dissection has a fundamental importance in the training of students and post-graduates and in refresher courses for consultants. Anatomy dissection therefore is not only the main instrument whereby we can directly know the human body, but it makes possible to learn basic and advanced surgery, to experiment new techniques and to streamline other increasingly complex ones. It is not by chance that in the syllabuses of doctors coming from more advanced countries at the scientific research and didactic organisation level, anatomy dissection is still foreseen as basic key teaching. This is also true for Italy, where, however, in practice there is considerable difficulty in carrying out practical exercises of this type; such difficulty is due to the lack of availability of bodies on which to carry out practical teaching, a lack which in turn derives from the scarcity of donation programmes for study and research⁶⁶.

Therefore, even though foreseen by the syllabus, anatomy dissections have in fact become very rare in most Italian universities. This is a situation that may seem even paradoxical: just in Italy, the cradle of anatomical studies in the sixteenth century, to the point of attracting students of medicine and professors from all over Europe to its universities, it is in fact extremely difficult to take part in practical lectures for medical-surgical training on

⁶⁶ This Opinion is dedicated, as in the title, to body donation for medical-surgical training, study and research. It also considers other aspects, which would also deserve an evaluation of a bioethical nature, such as body plastination and their exhibition in public places or the safety *crash test*.

bodies and anatomical parts. And, unlike what happened in the sixteenth century, in many cases the Italian surgeons had to go abroad in order to attend training and practical courses, with all the inevitable costs to be supported and understandable personal hardships.

In Italy also the promotion of a culture that is in favour of body donation for study and research and the adoption of suitable measures to legislate such donation would thus make it possible to significantly improve medical-surgical training. Furthermore, the great disparity would disappear between our medical-surgical community and the community of other countries, not only European ones, which on the contrary can rely on the considerable availability of bodies donated for scientific and teaching purposes. This is a need that has been felt unanimously by the surgeons of the various specialist branches, and expressed repeatedly in the publications of national congresses of the various scientific societies belonging to the Italian Association of Surgeons.

1. Historical references

With regard to the subject of medical training by practice on dead bodies, some historical outlines might be of use in more clearly identifying the ethical issues entailed. As already mentioned, during the sixteenth century under and post graduates in medicine of various European countries came to Italy in order to specialise in anatomy and body dissection, especially at the Universities of Padua, Bologna and Ferrara⁶⁷. Renowned scientists also came, like Andrea Vesalio the famous Flemish specialist, who upon completing his studies in Paris and Leuven and before being appointed as personal doctor to the Emperor Charles V, spent a number of years (1537-1542) in Padua teaching surgery with the use of anatomy and body dissection lectures. One of the reasons that attracted students and lecturers from various European nations was the possibility to practice on dead bodies in a continuous way. Dissections could be carried out just in the houses of the lecturers or in public places, both religious and laical, in the student colleges, at the groceries. The importance assumed by practice in dissection in the

⁶⁷ See G. Cosmacini, *Storia della medicina e della sanità in Italia*, Laterza, Roma-Bari (2010), pp. 82 et seq.

training and specialisation of doctors led to the construction of provisional anatomical theatres, set up for the duration of the lessons (for obvious reasons these took place during the winter) to be dismantled afterwards. The construction of the first permanent anatomical theatre was completed in Padua in 1594, after the architectural style of the amphitheatre; it was designed to allow students, seated high up on steps surrounding the dissection table, to carefully observe the operations and techniques of the professor. The same architectural design was then to be replicated in other anatomical theatres built in Europe, starting from the one in Leiden.

The question of finding bodies for dissection will be dealt with separately, as expressly regulated by the Venetian Republic, which every year had to supply the bodies of two people that had been put to death, one man and one woman, who had to be neither from Padua nor Venice. However the bodies were not always available or sufficient to satisfy the didactic needs of the anatomists; it was then that the “massari”, very capable students chosen by their classmates, had the job of procuring bodies otherwise⁶⁸. The modalities left a great deal to be desired as they could foresee the purchase of the body of a deceased relative from families in miserable conditions and in some cases even the forceful theft of bodies of persons belonging to minority groups, such as Jews. Sometimes the families that were chosen, despite their poverty, refused to “sell” the body of their relative and the resorting to violence to take away the cadavers understandably caused tension and terrible clashes in the university and city environment. It is interesting to see that in the attempt to avoid any kind of abuse, it was soon decided to celebrate public funerals for those whose bodies had been destined to autopsies in accordance with the regulations in force⁶⁹. It is even more interesting to recall the account of a famous student, Francesco di Sales, who decided to donate his own body to study and research. When he was a student of law and theology at the University of Padua in the first days of 1591, at the age of 23, he fell seriously

⁶⁸ For the above mentioned information, see the essays in the volume *Il Teatro Anatomico. Storia e restauri*, edited by C. Semenzato, with the collaboration of V. Dal Piaz and M. Rippa Bonati, Università degli Studi di Padova, Limena - Padova (1994).

⁶⁹ See M. Rippa Bonati, *Le tradizioni relative al Teatro Anatomico dell'Università di Padova con particolare riguardo al progetto attribuito a Fra' Paolo Sarpi*, in “Acta Medicae Historiae Patavina”, 35-36 (1989-1990), pp. 145-168, pp. 147 et seq.

ill following an epidemic. Francesco expressed his desire to his tutor, a priest, who had come to give him his last rites, for his body to be taken to the school of anatomy, so that “as I was not able to be of any use to this world during my life, I can at least be of some use after my death”. His intention was also to “prevent disputes and murders” between the medical students and the relatives of the dead⁷⁰.

These brief historical references show how during the course of the sixteenth century was established the awareness of the absolute need for anatomy dissection practice for the progress of research and the training of future doctors. The availability of bodies could satisfy different principles. Without considering the extreme and morally more serious possibility of body snatching, such principles can thus be summarised: 1) the primacy of the collectivity over whoever is sentenced with the charge of having been a threat to its security (hence the decision to use the bodies of those put to death for autopsies); 2) the reification of the corpse when it is considered that it can be sold or purchased, or even to give some kind of economic benefit to the relatives; 3) donation, the outcome of a conscious decision, like in the case of Francesco di Sales. Coming back to the present, the NBC’s opinion at hand means to highlight the importance of adopting the principle of donation both with respect to that of the primacy of collectivity, of which there are still some traces in our legislation, and with respect to a purely economic principle, which represents a form of instrumentalisation of the dead person’s body, and as can clearly be seen of the relatives and their state of poverty. The principle of donation in turn is associated with that of the respect of the person, even when that person is dead.

2. The legislation in Italy

In Italy body donation for study, research and training can find an indirect foundation in the constitutional principle of the development of culture and research (Art. 9), especially when this is functional in the protection

⁷⁰ See with regard to this *Histoire du bien-heureux François de Sales... Composée premièrement en latin, par son neveu Charles Auguste de Sales... et mise en François par le mesme Auteurs. Divisée en dix livres* A Lyon, chez François La Bottiere & Jean Juillard (1634), p. 31. When there seemed to be no more hope, Francesco slowly began to recover. After some weeks he was able to go back to his studies. He died in 1622 at the age of 55.

of health as a basic right of the individual and in the interest of the collectivity (Art. 32).

The specifically regulated authorisation can be found in Art. 32 of “Royal Decree” No. 1592 of 31 August 1933, (*Approval of the single text of the laws on higher education*) that sets down that: “dead bodies [...] whose transport is not covered at the expense of the relatives included in the family group to the sixth degree or by confraternities or associations able to take upon themselves the commitment for funeral transportation of the associates and those coming from medical-forensic ascertainment (suicides excluded) that are not requested by the relatives included in the above mentioned family nucleus, shall be reserved for teaching and scientific investigation”. The limit of such normative disposition lies in the fact that it establishes a sort of logic of exploitation by the collectivity towards the cadaver of totally unknown persons or of persons whose relatives and friends cannot be found.

A further legislative reference is given in the Mortuary Police Regulations (DPR 285/1990): “the giving to university anatomy lectures of bodies destined [...] to teaching and scientific research shall take place following the prescribed period of observation [...]” (Art. 40), which is 24 hours from the death (Art. 8). Furthermore, “the taking and conservation of bodies or anatomical parts, including foetal products, shall be carried out each time with the authorisation of the local healthcare authority” (Art. 41).

Undoubtedly, in the present state of things we cannot exclude the possibility that the bodies that are currently available belong to the ones who, before dying, consciously expressed such will in a signed document handed to a university facility, as demonstrated by significant experiences⁷¹. Nonetheless these are episodic events which find no follow up elsewhere, also owing to the “along general lines” legislation which does not deal with the many problems arising from body donation to university hospitals: modalities of the donor’s living consent, the binding nature of this, the prevalence or not of the privatistic concept over the publicistic one, the importance of the will of the

⁷¹ Such as the Body and anatomical parts donation programme, promoted by Raffaele De Caro, professor of Human anatomy at the University of Padua; the Centre for body donation for study and research (referee Lucia Manzoli, Professor of Human anatomy at the University of Bologna); the Laboratory for the study of the body, directed by Sarah Gino, Professor of Forensic Medicine at the University of Turin.

relatives, the guarantee of an efficient facility in the treatment of bodies and their conservation, in the preparation of didactic activity, the recomposition of the corpse and its successive return to the family, obligations concerning the procedures to be followed, identification of authorised regional research centres, etc. It is a question of identifying complex rules and procedures which on the one hand make it possible to realise a structured research programme on body organs, but on the other are accompanied by measures and proper arrangements that might ensure profound respect for the dead body. These are the reasons that over recent years have led to various bills of law⁷² on body donation for scientific research and professional training.

Moreover, it must be remembered that from the medical and study point of view all bodies can be donated to teaching activity and in many cases also to research, independently of the age of the dead person and their past state of health. Even the bodies of elderly people can in fact contribute to the study of senile pathologies. In addition, an integrative source of anatomical material could come from the organs or body parts that are taken away surgically and donated by patients for a temporary use in teaching and research, before being finally destroyed. Lastly, it must be remembered that the donation of one's body for study and research does not exclude the donation of organs for transplant; even though clearly having priority, this second form of donation is not therefore an impediment to the first.

3. Observations

3.1. The choice to donate one's body for research and teaching takes on a combination of symbolic meanings, such that the same choice becomes difficult both for the subject and his or her family. To imagine that one's own body can be "objectivated", cut and sectioned can raise a certain amount of psychological resistance, which can only be overcome by stressing the importance of donation and the good offered to others in the fostering of knowledge and scientific research. This special form of donation could be interpreted as one of the possible and original results of that ancient, exis-

⁷² These are bills of law C. 746 Grassi; C. 3491 Miglioli; C. 2690 Brigandi; C. 4273 Di Virgilio; C. 4251 Testa; all unified in 2012 in the text being debated in the last legislature (XVI) A.C. 746 Grassi and others.

tential and spiritual exercise, encouraged by Seneca, consisting in the “*meditatio mortis*”, an exercise that somehow indirectly manages to spread to the members of the family too.

At the basis of the decision to donate, which has psychological, emotional and affective reasons, deeply involving the cultural and symbolic level, lies the really crucial issue of *corporeity*. What does the body mean to us that exist? How can we imagine our body when we do not exist anymore, after our death? For a person that is alive, to think of his or her own dead body as a ‘corpse’ is an idea that is hard to accept. Here we pay for the inadequacy of our lexicon, even the juridical one, which is hinged on the person-thing distinction. On the one side, the dead body is not a person; on the other side of the coin it is not even a thing, since it refers back to the living body of a person who was such. The respect that we show towards the dead body is therefore respect for the dignity of the person, which comes from that corpse. The criterion of the continuity between living human being and inanimate human body should guide us in our ethical and juridical considerations; such criterion can also be traced back to the primitive forms of human and social organisation and is expressed by means of the cult of the dead, the respect that is due to them, the duty to give them a burial, which can also take on different modalities (entombment, interment and cremation). On the contrary, if the criterion of discontinuity is valid, the dead body very soon becomes a thing, *res nullius*, detached from the bond with the personal being of the living body.

Donating creates bonds between the donor and the receiver: the person who donates recognises the existence of the other. But if it challenges the logic of calculation and if it represents a victory of the symbolic over the biological, donation in the bioethical field raises some new questions, as whoever has analysed the difficult and significant interweaving of the gift, beyond the act of pure generosity well knows. It suffices to think of how in the ethics of organ donation there is the sense and acceptance of a tragic unavoidable destiny, of death, but together the will to overcome it, to react to it with a promise, a hope for life. It is what is realistically stated in the motto that highlights how, “This is the place where death delights to help the living” (*Hic est locus ubi mors gaudet succurrere vitae was moreover the phrase that was to be seen at the entrance of many anatomy rooms*). *In the ethics of donation - real ethics of hope - I give something to another person*

that is not irrelevant but a precious good, to which I attribute value (otherwise one would not speak of 'donation', like the anthropologists teach us with regard to the social meaning of the gift).

*In organ and body donation I take care of another person, in a caring altruistic sense. The principle of solidarity has thus exercised its great influence in directing the passage of legal systems from an idea of body-corpse linked to the affirmation of the principle of self-determination of the individual (and the consent of their family) to a so-called publicistic conception of the social value of organ donation, which valorises the moment of collective health. This approach expresses not only a way of rethinking the concept of the human body after death, but above all a different consideration of the person/society relationship. A good example of this is the silence-assent mechanism endorsed by various legislations, together with the Italian one (insofar as not entirely applied), which subjects anyone to the possibility of an *ex mortuo* explant, except in the case of the manifestation of an explicitly expressed will to the contrary. Such solution however shows a worrying obliteration of the now established principle of informed consent, of the consciousness of the gesture that is made and the value of what is being donated. The fact must not be underestimated that the legislations that adopt such system, and Italy is certainly one of these, come across considerable difficulties in foreseeing and realising streamlining and ascertainment procedures of such silence-assent, procedures that are aimed on the one hand at guaranteeing greater awareness by the citizen with regard to the meaning and consequences of their choices and on the other at making the will of the subjects more comprehensible.*

For these reasons the Committee considers that the principle of information and the consent of the subject to the donation of his or her organs and body must be considered as having priority and that this cannot be substituted with a model of collective and generalised information, anchored to the silence-assent principle. If this latter model were adopted, the legislator's predicament would be even more difficult, as he would want to establish a sort of duty of solidarity, without declaring it explicitly and taking advantage of the ambiguous rule of the individual's presumed consent. The NBC therefore retains that in this context the private and public dimensions must be considered as complementary rather than in opposition. Together with the privatistic discipline, functional in fostering the principle of respect of the person and his/her autonomy with regard to the possible donation of the body for study

and research, a publicistic discipline should concur; the function of the latter should be that of guaranteeing the due controls to give support to the same autonomy, to avoid possible abuse and to ensure the necessary protection so that the respect for the continuity of the person is effective also after death, especially when it is a question of the body of a person without close family or friends with authorised persons acting on behalf of their safeguard.

3.2. Unlike the donation of organs (Act 91/1999), the regulation of body donation for study and research does not involve complex procedures; besides the obvious ascertainment of death and the absence of legal reasons for withholding the corpse, it must foresee the express will of the donor through written provision of his/her will to this effect or by the signing of a special register even in electronic format. Such will should always be considered revocable and renewable in time. The act of donation could foresee the giving of the body for study or research and for teaching or both, as well as the definition of the time for its return to the family. It could also foresee the consent to the taking of anatomical parts, such as the encephala which is of great interest for the study of a number of pathologies (for example, Parkinson's and Alzheimer's disease) or the request to limit the research and dissection only to some parts of the body. With regard to this last point the fact must not be underestimated that there could be some amount of reluctance to donate one's body to research, owing to the psychological resistance in imagining that some parts, for example the face, considered as being particularly significant for the symbolic, identity and relational importance that these represent for the subject, can become the object of dissection and considerably alter the appearance of the corpse. Therefore to deny the possibility to limit the research and dissection to some parts of the body could appear as little respectful of the will of some potential donors, besides considerably affecting the number of the donations.

As far as concerns the question of anonymity, this is quite different with respect to donation aimed at organ transplant, in which it is rightly foreseen as being compulsory; in the case of donation for study and research, the possibility to remain anonymous should lie with the donor's will, even if failing to do so could have a positive effect of clearly indicating to specialists, doctors and the media a possible gesture of solidarity to be imitated, it should be made known to the public.

The donor's will could be also included in advance directives (or living will), these should be recognised as a legally valid document by the Italian legislator. The involvement of the family is opportune. It is in fact fundamental that the donor is aware of the repercussions at emotional and psychological level that their choice can have on those nearest and dearest to them and that they do all that is possible so that the latter accept and hopefully appreciate such choice, without prejudice to the fact that the respect for their will cannot be subordinate to consent or to the non opposition of the family members. The role of the family can be important also to make the donor's will executive. The appointment of a trustee may then be opportune, capable of interacting with the medical facility and becoming the obligatory referee for the beginning, duration and cessation of the study of the body, above all bearing in mind the donor's *desiderata*. Even before this, at the moment of the donor's death, it is opportune that the trustee or, if the trustee is not yet appointed, a relative notifies the healthcare facility that is to receive the body. After the funeral the body will be transported to the same facility; when the time allocated for the study and anatomy lectures has expired, the corpse, carefully recomposed, will be returned to the family in a reasonably short space of time. Transport services should be charged to the healthcare facilities that received the body; should there be no relatives or friends to whom to return the donor's body, burial will anyway be guaranteed by the state.

It goes without saying that the facilities for accepting donations must give suitable guarantees with regard to the conservation of bodies, their didactic and research use and their treatment, always based on the full respect of the person, the deadlines for their return and the absence of any form of profit whatsoever; this implies that the combination of such activities and the complex procedures that they involve can be developed only in highly specialised university and hospital facilities, which the Health Ministry will undertake to define as centres of reference. It is fundamental also to start suitable information and awareness campaigns not only among citizens, but also in the medical profession itself. Such measures, or rather the restriction of the activities to highly specialised reference centres, with the guarantee of the due respect of certain qualitative and ethical standards, on the one hand and an information campaign on the other should foster the strengthening of the donation culture over time, which in the case in point finds ex-

amples in the values of solidarity and the promotion of research and science. As it has movingly been said, it is “the last possible gift”⁷³ that one person can offer to others.

Recommendations

1. Body donation for teaching and science purposes is the expression of the values of solidarity and the promotion of culture and research aimed in turn at the safeguard of health (Const., arts. 9, 32). It must be stressed that the donation of the body is important both to increase research and knowledge and to improve medical-surgical training, objectives that allow both to guarantee a more efficient safeguard of the patient’s health.

2. The *post mortem* body, by reason of its bond with the person and its symbolic and affective value always and anyhow deserves respect; the various organisational procedures and any normative solutions must always draw from such principle, fostering donation for study and research purposes.

3. The principle of the donor’s conscious and informed consent must be considered fundamental, and cannot be substituted by the silence-assent principle.

4. What is foreseen in art. 32 of “Royal Decree” No. 1592 of 31 August 1933, must be considered ethically unacceptable, or that is the destination to teaching and study activities of the dead bodies of persons who are completely unknown or with no relatives and friends, unless these same people have expressed their consent to donation.

5. Donation cannot be subordinate to the consent or the non-opposition of the family at the moment of the donor’s death. It is nonetheless to be hoped that the choice to donate is shared by the family and that it is suitably involved in the different phases, starting from reaching of the donor’s decision. The role of the family can be important also in the execution of the donor’s will. The nomination of a trustee could then appear opportune, capable of interacting with the medical facility and becoming the obligatory referee for the start, the duration and the cessation of the study activity of the body, above all bearing in mind the donor’s *desiderata*.

⁷³ G. Mattutino, *L'ultimo dono possibile*, in ‘Socrem News’, No. 3, Sept. 2008.

6. The act of donation can foresee the limitation of research and dissection only to some parts of the body. It can furthermore foresee the destination of the study of the body either to research or didactic purposes or to both, as well as the definition of the deadline for the return of the body to the family. The research institute receiving the body has to give suitable guarantees with regard to the date for the return of the body and the absence of any form of profit.

7. It is important to start awareness campaigns to foster body donation for research and teaching, stressing its relevance for the improvement of medical-surgical training.

ATTACHMENT I: Query by Hon. Roccella

Rome 16 April 2012

Prof. Francesco Paolo Casavola
President of the National Bioethics Committee

Dear President,

I would be grateful if you could consider the query that I would like to submit to the National Bioethics Committee on the issue of body donation for study and research and on the possible critical points and problems for its regulation.

Thank you for your kind attention.

Yours faithfully,

Hon. Eugenia Roccella
*Member of the Social Affairs Committee in the Chamber of Deputies,
Member of the Parliamentary Intergroup for the value of life.*

Rome 16 April 2012

The possibility to use human bodies for study and scientific research represents a precious opportunity for all whether they be specialists, experts or students, and consequently for the whole society, which can benefit from the results of research. The modality whereby each citizen can donate their body to scientific research needs to be regulated very carefully nevertheless, like the ones whereby researchers can use available human cadavers and the results obtained from their studies, so as to first of all avoid any forms of commercialisation of the human body or parts of it, and more generally, to avoid treatment and procedures that do not respect the dignity that our culture recognises the dead body.

At present a bill is being debated in Parliament that could regulate the matter in question: it would be useful for the National Bioethics Committee to express its standpoint with regard to the issue of body donation for study

and research too, so as to identify and clarify possible areas of major concern and problems of legislation from an ethical point of view.

Hon. Eugenia Roccella

Presidenza del Consiglio dei Ministri



**MENTAL DISABILITY IN DEVELOPING
AGE AND AUTISM⁷⁴**

19 April 2013

⁷⁴ Only the conclusions of the present Opinion have been translated into English.

General Conclusions

Having completed the analytical examination of the major scientific, bioethical and legal issues related to the “autistic spectrum”, the NBC now repropose in a concise and unified way the conclusions reached in the debate, advancing proposals for the further promotion of knowledge of this complex syndrome and for the improvement of the living conditions of people with autism and their families. Moreover, the phenomenon of the increase in incidence (real or presumed?), probably due to multiple factors, including also the improvement of diagnostic capabilities (according to current data until 1:88 or even 1:50, according to some case studies) is an item of data that must be taken into serious consideration.

From the point of view of the contribution of biological and neuroscientific research, the most important aspects which seem to emerge are the following:

1. Understanding of the genesis of the autistic disorder has progressed in recent decades, through comparative research between the behaviours of healthy subjects and subjects with autism, observed during the trajectory of child development, adolescence and adulthood.

A number of different factors have been recognised as being involved in determining personal autistic behaviour with obvious repercussions on social behaviour; also the techniques of modern neuroimaging and neuroanatomical investigation [e.g. structural and functional magnetic resonance imaging (MRI and fMRI); PET (Positron Emission Tomography); EEG (electroencephalogram), etc.], applied to both the subject with autism and to the equivalent control subject, have identified various structures that are activated in the course of development in relation to vital and environmental stimuli, at times of a varying degree between normal subjects and subjects with autism.

2. Despite the lack of extensive anatomopathological documentation, research in the last decades has, however, allowed to establish the brain regions and structural brain nuclei most involved in the “autistic spectrum” and to recognise the characteristics of the connections between the different structures (functional circuits), appreciating their efficiency always by means of comparison between autistic and normal subjects. The set of data generally indicates defects in connectivity in the autistic subject, which affects both the systems that govern certain cognitive aspects and affective aspects of the mind.

3. Sufficiently clarified is the epidemiological data, the prevalence of males, frequent family history, the amplitude of personal variations in symptomatology, etc., so that today autism forms part of a “phenotype” present in each human population.

4. The prevalent search for causative factors gives prominence to the genetic factors that regulate early ontogenesis of cerebral personal life: stem cell activity, the function of interneuronal cells, the processes of neuronal migration; those of receptor response to neural stimulation by neurotrophins; the micro-columnar structures which allow for correct function and finally the processes of excitatory and inhibitory specialisation of neurochemical transmission at synapses.

Increasingly consistent research interest has been devoted to the study of the biology of the neuron in autism: features of the axon, myelination, training and development of dendrites, number and structure of the spine and finally the neurochemistry of synapses, with interesting zonal differentiation.

Even conventional “genetic” research has paid off, despite still being subject to continuous progress in relation to the development of techniques: of the approximately 250 genes considered to be “involved”, about thirty have been recognised as having a greater role in the control of altered functions on the neuronal cell level, of synapses or glial structures of connection, even through the analysis of microdeletions, repetitions of triplets and other anomalies, once not suspected as a possible basis of the symptomatologies of autism and those commonly associated with it (mental retardation: RM; epilepsy. states of anxiety, etc.). This research must be pursued by documenting in parallel and with unexceptionable rigour the clinical conditions of the person concerned.

Lastly, an interesting investigation has been started into cerebral “zoning” in the expression of genetic functions, of gene transcription and protein metabolism: this study will probably bring about exciting progress in the future.

Finally, benefits are gained - although to a lesser extent to that initially hypothesised - from the symptomatic and behavioural similarities produced experimentally in mice and non-human primates in the context of human autism. This line of research should be pursued for the possible positive effects in the identification of pharmacologically useful molecules for therapeutic purposes.

To conclude on the role of this highly developed area of study, it can be said that - at the stage reached by research - the framework for “essential” autism (i.e. non- symptomatic and forming part of the broader etiologic and diagnostic structure of other diseases), corresponds to the intervention of multiple genetic factors, whose variation from the norm causes different effects on the level of the microstructures of the brain (neurons, synapses, glia, etc.) and related functional consequences (the genesis of abnormal proteins, etc.).

5. There is increasing interest towards consideration of pathogenic factors defined as environmental that act during the course of intrauterine life and with which - be they of maternal origin, or broadly of environmental origin - the baby comes into contact. These factors may act on a designated genetic level and give rise to a cascade of dysfunctional events even some time after birth.

In this regard, not to be forgotten is the close functional correlation between the nervous system (the central one in particular) and the immune system, which the research of the past decades increasingly considers as being “integrated” in the defense and promotion of the “internal medium”, contrary to the old theory of isolation provided by the “blood- brain- barrier”, a theory which today is no longer sustainable.

Further research in this area must be carried out, even as regards greater accuracy in the collection of clinical-epidemiological factors.

6. In recent years, in parallel with the development of the “functional biology” of the nervous system and investigation into its behaviour in the “autistic spectrum”, a more extensive form of neuroscientific reflection has emerged which does not shy away from considering the “classic” issues of the mind, of SELF awareness, of formation of one’s own awareness of things as well as that of others even in the mentally disabled during infancy, and the course of pre-adolescent development, which investigates emotion and rationality, responsibility and the sense of good and evil. Laboratory tests, consistent with clinical observation show in the majority of cases, not an absence of reactions, but rather a slowdown of the genesis and the development of response.

7. Theory of Mind, Theory of mirror neurons, Theory of central coordination and finally Theory of the lack of connectivity can be considered as different angles of interpretation of a reduced profile of some (but not all) of

the neurological functions chiefly involved in the social behaviour of the person with autism.

From the perspective of bioethics and bio-law, essential recommendations can be summarised as follows:

- to promote the fostering of research on the development of autism spectrum disorders during the cycle of life and on treatments also appropriate to adulthood in a translational research which bridges the gap that exists today between the advancement of knowledge both biological and neuroscientific in the laboratory and “field research”, in which it is necessary to standardise the rules of communication and “counterproof” according to the latest criteria of objectivity;

- to guarantee the right to a conscious choice of care, through the request for informed consent to the parents or to the subject, in the case of this being an adult capable of expressing consent, before each treatment - assuming that any treatment can, if there is no hypothesis of reliable effectiveness for that reason, be a harmful waste of time and energy - the request must provide thorough information on the different treatments available and the related assumptions of effectiveness;

- to guarantee the right to health care through the verification and maintenance of diagnosis, and to ensure continuation of educational-interventions appropriate to the pathology and to age throughout the whole trajectory of life;

- to resort to pharmacological interventions solely in the interests of the person;

- to ensure the right to development of capacity not limited to providing the adolescent and young adult with autism merely a targeted executive capacity, but also providing a suitable cultural preparation according to the ability demonstrated by the individual;

- to not waste the results of possible improvement of executive capacities, obtainable with some of the habilitation techniques, this can be achieved by increasing the chances of employment through economic and social policies aimed at people with disabilities, organising ad hoc mentoring services and reacting to any form of “stigmatisation”.

To this end, it seems appropriate to:

- a. encourage the formation of more specialised support teachers of various types and grades of school education;

b. encourage the creation of social cooperatives that make provision for a percentage of individuals with disabilities;

c. favour the establishment of day care centres that promote integration and work activities, according to personalised educational-habilitation programs, synergising with psychiatric services;

d. promote and monitor at the same time the rise of protected communities for adults with severe autism, overseeing the assurances given about the quality of services, the training of personnel, the organisation of the facility, in order to ensure the best quality of life and greatest possible independence for the persons they are intended for.

Lastly, it is right to take care of the families of persons with autism through *ad hoc* social policies, ensuring their welfare and economic support.

The combination of these measures is justified by the consideration of autism, as in general with physical and mental disabilities, not according to a medical classification in the strictest sense, but according to a complex perspective, of a bio-psycho-social nature.

The -bio-psycho-social approach to disability brings - in turn - acceptance of a perspective of bioethics, which can be construed as the *bioethics of care and solidarity*, which takes charge particularly of the disabled for the additional vulnerability that their condition involves. This bioethics examines not so much the occasional problems of the dilemmas between principles - which also exist - but rather “the problem” which is unacceptable of the discrepancy between the affirmation of universally shared principles - found in the Declarations of International Organisations as well as in our legal system - and the lack or the inadequacy of their actually being implemented.

Bioethical reflection leads, therefore, not to argumentation and affirmations as to “which” ethical principles should prevail, but to “recommendations” on best practices for the implementation of principles that are as shared in theory as they are in practice disregarded or incompletely respected. Ultimately, a bioethics that bends from the theoretical level to the analysis of reality, listening to the voices that come from the world of autism, their repeated complaints about the many rights not realised, to call for greater ethical-political commitment for the “care” of persons with autism.

To sum up what has emerged during auditions from the dutiful “consultation” of experts, but also of those working “in the field” and families

(especially parents), now universally recognised as “essential” elements in the habilitative process of childhood and early adolescence of the person with autism, is the ascertainable passion and suffering that characterise these people, as well as their determination to continue their educational role.

At the legislative level, there has been a steady improvement over the last few decades of the general and special “framework” in which to view the help offered by the State - even in relation to a favourable evolution in public “opinion” in many European countries, towards affirmation of the dignity of the autistic and the elimination of discrimination and stigmatisation. The awareness of this undeniable increase in protection and sensitivity has also been reaffirmed in the “auditions”, accompanied, however, by a deep disappointment regarding the shortcomings in the implementation of various laws.

The text of the Opinion contains several comments, evaluations and requests (along with the relative proposer) which emerged during the “auditions” which highlight the great local variability in the organisation of care and support still existing today in Italy. Reference is made to the text for the important observations that were collected.

Moreover, all those intervening showed great awareness of their educational role to which they intend to give the best of their ability, calling however, with dignity for the sympathetic support of the civil Community and the State.

Even the Document: “Guidelines for the promotion and improvement of the quality and appropriateness of care interventions in the field of pervasive developmental disorders (PDD), with particular reference to the appearance of autistic disorders” - published November 22, 2012 - is a solemn attestation of the will to proceed, even in the current budget difficulties, with improving, within the different local realities, the response to the needs of children and adults with autism, and those of their families.

The NBC hopes that even in the current legislature the same attention will be given to the problems of disability. However, it expresses deep concern regarding the risks of excessive regulatory fragmentation. It would be advisable to favour legislation that is unitary by principles, and which leaves to regulatory and/or administrative processes, its adaptation to specific circumstances and needs.

Presidenza del Consiglio dei Ministri



**ILLEGAL TRAFFICKING OF HUMAN ORGANS
FROM LIVING DONORS**

23 May 2013

Presentation

The existence in the world of illicit trafficking in human organs for transplantation is a dramatic event that represents a real danger to public and individual health and violates fundamental rights and human dignity. The general impression is that, both at national and international levels, effective tools to prevent, reduce and combat this criminal activity have not yet been adopted. This illicit affair unavoidably involves also the scientific community (surgeons, nephrologists, those in charge of transplant centres, resuscitators, etc.). It must be added that the victims of this market are with increasing frequency vulnerable persons such as prisoners, those sentenced to death, minors (children abducted in order to acquire organs). Especially in the last few decades, the flow of organs and body parts proceeds along the modern international routes traced by capital: from South to North, from the third world to the first world, from the poor to the rich. At its worst this trafficking turns into forms of expropriation, exploitation and coercion.

The World Health Organisation on multiple occasions and over the years has called on States to take measures to protect the poorest individuals and vulnerable groups from transplant tourism and the sale of organs. Currently, the Council of Europe in the process of preparing a Convention aimed to suppress the trafficking of human organs and to formulate an international legal instrument (*Projet de convention du Conseil de l'Europe contre le trafic d'organes humains*). The preparatory study recommends as of now that on the one hand there is the need for national legislature to provide for sanctions even of a criminal nature, and on the other the promotion of a more specific international convention against trafficking *strictu sensu*, so as to identify the presuppositions and conduct that characterise and define it.

Like other European Countries, even Italy, despite regulations on a number of cases related to organ transplantation, has a modest system of sanctions with regard to illegal trafficking of organs. The two main regulations (Law No. 458, on 26. 06. 1967 on living donor kidney transplantation and Law No. 91 on 1. 04. 1999, on the removal of organs and tissues from cadavers) provide for sanctions exclusively for those carrying out mediation and health professionals that use the organs derived from this commercial trade, but no penalty is provided for with regard to other parties directly or indirectly involved in this illegal trafficking.

The Committee does not intend in this document to specifically analyse the problem of illicit trafficking in organs with exclusive reference to the Italian situation, but rather it wants to address the problem on a general level, prompted by the current reflection and exploration of the Council of Europe. This reflection and investigation at a transnational level, is addressed to individual States, in the belief that only by means of consistent and coherent regulations on a national and international level will it be possible to give a strong response to this widespread phenomenon.

In addition, considering that the market for human body parts presents multiple and various issues depending on whether it is a trade between living individuals or derived from cadaver donation or involving body cells and tissues, the Committee believes it to be appropriate to limit the Opinion to the trafficking of organs from a living donor, specifically the kidney, which now appears to be the organ that is most prevalent on the market.

Having stated this, the conclusion reached by the NBC in the majority of its members is that although the idea of regulation is difficult to achieve in the social and medical reality of many parts of the world, especially in poor countries, Europe at least should provide for legal regulation that is international and national with the introduction also of types of criminal offense, aimed at defining the trafficking in organs, to prevent it, to enforce the principle that the human body or its parts are not for commercial trade.

For this purpose it is hoped that States will work together on an international level to improve the practice of transplantation and organ donation and cooperate, in compliance with relevant international instruments and national law, as far possible in order to carry out investigations in relation to any offense committed on its territory and outside of it. In addition it is necessary to establish by agreement, with multilateral treaties based on the principle of double incrimination, mutual recognition of this type of offense, in order to ensure adequate collaboration between the requesting countries and the countries in which the act was intentionally committed.

The Opinion, drawn up and edited by Adriano Bompiani, Lorenzo d'Avack and Laura Palazzani, was approved at the plenary session of 23 May 2013 and also approved by Salvatore Amato, Adriano Bompiani, Stefano Canestrari, Antonio Da Re, Lorenzo d'Avack, Carlo Flamigni, Romano Forleo, Laura Guidoni, Assuntina Morresi, Andrea Nicolussi, Laura Palazzani, Alberto Piazza, Rodolfo Proietti, Monica Toraldo di Francia. Cinzia

Caporale and Vittorio Possenti abstained. Luisella Battaglia, Bruno Dal-lapiccola, Maria Luisa Di Pietro, Riccardo Di Segni, Silvio Garattini, Marianna Gensabella, Demetrio Neri, Giancarlo Umani Ronchi and Grazia Zuffa were not present at the time of voting and subsequently approved the Opinion.

Attached to the Opinion is the personal remark written by Luisella Battaglia, Lorenzo d'Avack, Silvio Garattini, Rodolfo Proietti, Vittorio Possenti, Lucetta Scaraffia by which they wished to draw the attention of the NBC to the position of the doctor or medical facility in the Country of origin, assigned with the duty to provide therapy and assistance, when requested by that patient-buyer who has acted clandestinely.

The President
Prof. Francesco Paolo Casavola

Premise

1. Organ transplantation has marked in the process of development of modern medicine one of the most important and meaningful turning points, permitting to prolong and improve the lives of patients all over the world. Especially organ donation from a living donor is considered as a supererogatory act and as such is therefore worthy of extremely high ethical appreciation, in view of the goal of solidarity that it intends to accomplish.

However, the emphasis has been on the objective dangers that are linked to this practice, so as to recommend that such a procedure always remains an exceptional circumstance, as well as ensuring the total freedom of the donation and that any and every commercialisation is fought in principle and in fact.

These principles are not always adhered to and there are many reports of “illegal organ trafficking.” An unlawful act that is not always well defined in state legislation, confused with other types of criminal cases, comprising in this expression not only the buying and selling of organs and so-called ‘transplant tourism’ (patients from rich countries who travel abroad to purchase organs from poor people), but also the activity of intermediary organisations aimed at the illegal sale and the trafficking in human beings for the purpose of removal of organs. This helps neither the prevention nor the repression of the crime.

Then there are governments that avoid carrying out transplants on their own territory forcing their patients to go abroad, despite knowing that these are vulnerable countries, assenting to reimburse the cost of the operation, because everything is much easier and less expensive. Poor countries are the focus of the market, there are different prices for organs for the buyer in various parts of the world and equally variable is the remuneration for the donor.

This ethically and juridically illicit affair unavoidably involves also the scientific community (surgeons, nephrologists, those in charge of transplant centres, resuscitators, etc.). Added to the fact that the victims of this market are with increasing frequency vulnerable persons such as prisoners, those sentenced to death, minors (children abducted in order to acquire organs). Especially in the last few decades, the flow of organs and body parts proceeds along the modern international routes traced by capital: from South to North, from the third world to the first world, from the poor to the rich. At

its worst this trafficking turns into forms of expropriation, exploitation and coercion. The data published by the World Health Organisation indicate that one-fifth of the 70,000 kidneys transplanted come from an economic transaction⁷⁵.

The worldwide existence of illicit trafficking of human organs for transplantation is therefore an indisputable fact. It is not easy to obtain ‘official’ data given the clandestine nature of the phenomenon. The general impression is that, both at national and international levels, effective tools to prevent, reduce and combat this criminal activity, which represents a real danger to public and individual health and violates fundamental rights and the dignity of man, have not yet been adopted.

2. In relation to this matter at least two different options in legal terms can broadly be found: one that believes that the body may be an object of free trade regulated by the State⁷⁶, the other instead believes that it is not commercially tradeable establishing buying and selling as illegal.

From the analysis of national laws (including our own) and regulations and international conventions⁷⁷ it emerges as a prevalent fact that the body is excluded from market relations. Consequently, the need to combat the illegal trafficking of organs has become both on urgency and a priority.

The World Health Organisation on multiple occasions and over the years has called on States to take measures to protect the very poor and vulnerable groups from transplant tourism and the sale of organs⁷⁸. To address the urgent and growing problems associated with the organ trade, in May

⁷⁵ Indications regarding the publication of the Council of Europe, “Transplant Newsletter”, 2010, vol. 15.

⁷⁶ The *Universal Declaration on Human Rights* (1948), the *Convention of the Council of Europe on Human Rights and Biomedicine*, 1997, Articles 19, 21 and 22, the *Additional Protocol to this Convention concerning transplantation of organs and Tissues of human Origin*, 2002, Arts. 21, 22, the *Charter of Fundamental Rights of the European Union*, 2000, Article 3.

⁷⁷ The *Universal Declaration on Human Rights*, 1948, the *Convention of the Council of Europe on Human Rights and Biomedicine*, 1997, Articles 19, 21 and 22, the *Additional Protocol to this Convention concerning transplantation of organs and Tissues of human Origin*, 2002, Arts. 21, 22, the *Charter of Fundamental Rights of the European Union*, 2000, Article 3.

⁷⁸ *Resolution 44.25/1991, Resolution 57.18/2004 and Resolution 63.22/2010.*

2008, a summit was held in Istanbul with more than 150 representatives of scientific and medical organisations from all over the world in which a declaration was made (*the Declaration of Istanbul on the trafficking of organs and transplant tourism*) in order to obtain a legal and professional framework governing organ donation and transplantation activities, as well as transparent supervision by a regulatory system which guarantees the safety of the donor and recipient and respect for human dignity.

Currently, also the Council of Europe is in the process of preparing a Convention aimed to suppress the trafficking in human organs and to formulate an international legal instrument (*Projet de convention du Conseil de l'Europe contre le trafic d'organes humains*). The preparatory study recommends as of now that on the one hand there is the need for national legislature to provide for sanctions even of a criminal nature, and on the other the promotion of a more specific international convention against trafficking *strictu sensu*, so as to identify the presuppositions and conduct that characterise and define it.

This practice of illegal trafficking, as mentioned, exists alongside the parallel trade in slaves, children, women, the so-called trafficking in human beings. Therefore, the dissent against organ trafficking is contained not only in the above-mentioned protocols and conventions that explicitly condemn it, but also in the provisions and regulations relating to the incrimination of exploitation and human trafficking⁷⁹.

1. Legislation in Italy

The rules governing transplants from living donors and from cadavers has progressively involved a series of regulatory provisions: Law No. 235, of 04/03/1957 (removal of body parts from cadavers for therapeutic trans-

⁷⁹ The *UN Convention on the Rights of the Child*, 1989, the *Additional Protocol to the UN Convention against Transnational Organized Crime to prevent, suppress and punish trafficking in persons, especially women and children*, 2000; *Optional Protocol to the Convention on the Rights of the Child on the Sale of Children, Child Prostitution and Child Pornography*, 2002, *Council of Europe Convention on Action against Trafficking in Human Beings*, 2005; *Council of Europe Convention on the Prevention of Terrorism*, 2005 and the *Council of Europe Convention on the Protection of children against Sexual Exploitation and Sexual Abuse*, 2007, the *EU Directive on Standards of Quality and Safety of Human Organs Intended for Transplantation*, 2010.

plant purposes); Law No. 458 of 26.06.1967 (living donor kidney transplants); Law No. 644, of 2.12.1975 (removal of parts from cadavers for therapeutic transplant purposes); Law No. 301 of 12.08.1993 (removal and grafts of cornea); Law No. 91 of 04.01.1999 (removal and transplantation of organs and tissues); Law No. 483 of 16.12.1999 (partial liver transplantation) and Law No. 167 of 19.09.2012 (partial transplantation of the lung, pancreas and intestine from living donors).

A gradual legislative tendency to reduce the limits of this health care practice becomes apparent, moving in the direction of broadening the scope of lawfulness. Especially Law No. 91 of 01.04.1999 regulated the subject of transplants from cadavers in three ways: one with regard to the facilities and organisational aspects, another related to the safety of transplants, and the other concerning the method of formulation of the consent to removal.

However, a lack of regulation and a reduced system of sanctions with regard to the illegal trafficking of organs is to be noted. Law No. 458 of 26.06.1967 on living donor kidney transplant at Art. 6 provides that “any private stipulation providing for monetary compensation or other benefits in favour of the donor, to induce him at the time of disposition or destination is null and of no effect” and at Art. 7 provides for imprisonment from three months to one year and a fine ranging from 100,000 Lira to two million Lira to anyone who for financial gain acts as an intermediary in the donation of a kidney. Law No. 91, of 1. 04. 1999 on the removal of organs and tissues from cadavers provides for more severe penalties for anyone who procures for financial gain an organ or tissue from a person declared to be dead or more precisely acts for commercial trade: imprisonment from two to five years and a fine ranging from 20 million Lira to 300 million Lira, as well as perpetual interdiction from the exercise of the profession if the offense is committed by a person engaged in the healthcare profession. The penalty is more limited against those who commit the crime without any financial gain.

In both regulations the penalties provided for are therefore borne exclusively by those engaged in the mediation and by the health care worker that uses organs deriving from commercial trade, but no penalty is provided for as regards other parties directly or indirectly involved in the illegal trafficking.

2. Considerations⁸⁰

The Committee does not intend in this document to specifically analyse the problem of illicit trafficking in organs with exclusive reference to the situation in Italy⁸¹. The NBC wants to address the problem on a general level, prompted by the current reflection and exploration of the Council of Europe. This reflection and investigation at a transnational level, is addressed to individual States, in the belief that only by means of consistent and coherent regulations on a national and international level will it be possible to give a strong response to this widespread phenomenon.

Moreover, given that the market for human body parts presents multiple and various issues depending on whether it is a commercial trade between living individuals or derives from cadavers or involves body cells and tissues, the Committee considers it appropriate to limit the Opinion to the trafficking of organs from a living donor, specifically the kidney, which is currently the most prevalent organ on the market.

Having stated this, the following is to be pointed out.

a) The Committee considers it essential to have a precise definition of the case in point and proposes that “organ trafficking” should include all those activities which, through the use of force, threat, coercion, abduction, deception, abuse of power or exploitation of a position of vulnerability, particularly economic vulnerability, are aimed at obtaining and removing organs from a living person. The payment of sums of money or other benefits to the donor or third party, either directly or through intermediaries also falls within this category.

⁸⁰ The NBC also recalls the many Opinions previously expressed on the subject of organ donation: *Bioethical aspects of aesthetic and reconstructive surgery*, 2012; *Kidney donation from a living donor to a stranger (so-called Samaritan donation)*, 2010; *Criteria for the ascertainment of death*, 2010; *Motion on the sale of organs for transplantation*, 2004; *NBC Opinion on the proposal for a moratorium on human xenotransplantation clinical trials*, 1999; *The bioethical problem of the kidney transplant from a non-blood related living donor*, 1997; *The anencephalic infant and organ donation*, 1996; *Organ donation for transplantation purposes*, 1991; *Definition and detection of human death*, 1991; *Donation of the corpse for scientific research*, 2013.

⁸¹ The National Transplant Center, queried on this point, however, referred to the NBC in a statement that, to date, from the available data that do not appear to be drop outs from the waiting lists without any traceable follow up.

Trafficking in organs often leads to so-called “transplant tourism” whenever there is a movement of organs, donors, recipients and specialised personnel (doctors, health care workers) across jurisdictional boundaries without authorisation from either their own Country or that of the place where the removal and implantation is carried out.

This matter involves different categories of people: sick patients, often already on dialysis as regards kidneys, willing to travel great distances and face risks to their health in order to get the transplant they need; the sellers are generally poor and in dire straits; the surgeons and medical facilities, are willing to break laws and the fundamental rules of ethics and deontology; the brokers and other intermediaries who have links with the underworld of organ trafficking and finally the doctors who in the Countries of origin provide care to patients that have made use of this market.

The Committee reiterates, as in other documents⁸², primarily the condemnation of the commercial trade of the body as a violation of the fundamental rights to personal integrity and to health, and recommends that national Countries and international bodies should prepare regulations aimed at better containing and combating this illicit affair; to counteract and discourage the demand, punishing those who buy organs for themselves or for others, even through the configuration of specific crimes to protect the rights of the victims of these offenses; the promotion of the donation of organs, as well as the promotion of international cooperation in order to improve the practices of organ donation and transplantation.

b) As for the patient-buyers of organs, even if they are seriously ill and more or less prompted by reasons of urgency, it does not appear lawful to the NBC that they may be exempted from criminal liability when, directly or indirectly, they take possession of the body parts other people, taking advantage of the poorest and most vulnerable individuals. In the transplants from living donors this practice, if justified, endorses the idea that certain individuals do not have equal dignity and that they are merely items that can be disposed of to benefit others. Nancy Scheper-Hughes, who for many

⁸² Cf. footnote 6.

years has been fighting against the organ market, points out that this commercial trade begins the moment a weak and sick person looks at another individual, realising that there is something inside of that individual that he/she needs and which may lengthen his/her life⁸³. A defined form of “neo-cannibalism” that considers the body of others as a source of disassembled spare parts with which to prolong our lives. Faced with the need to protect one’s own health it is easy to give space to a “grey area” in the field of ethics, where established principles are put into question in favour of the state of emergency, and listen to the casuistries of self-justification of mere opportunity or self-interest.

Therefore, the NBC believes it necessary to prepare for a more vigorous repression of a phenomenon found to be incompatible with ethical and fundamental juridical values, and that our legislators should provide for the extension of criminal liability even toward the buyers, in order to translate juridically the moral gravity of their actions, also with the purpose of deterrence. Despite the great diversity of situations and cases, the law is called on to establish a general principle that strongly condemns organ trafficking even with regard to patient- beneficiaries who willfully do not respect the shared system at a national level. The NBC believes that in some instances it would be an effective deterrent for anyone if one had to face the prospect that, the purchasing of an organ to improve one’s own health conditions, could lead to the real risk of being criminally charged on returning home from abroad.

In this context, involving the trade of organs from a living donor, additional instances of crime can be integrated, such as the crime of murder in the event of the occurrence of the death of the victim, or some aggravating or mitigating circumstances as provided for by the penal code for other offenses. In this particular case the principle of the importance of the consent of the person involved, being of sound mind and will, must not be applied as a cause of exclusion from the anti-juridical nature of the event⁸⁴.

⁸³ N. Scheper-Hughes, *Organ trafficking in the global market*, Ombre Corte, Verona, 2001.

⁸⁴ Therefore the provisions in Art. 50 of the penal code cannot apply in this case (Consent of the person entitled): “Whoever violates or risks someone’s right is not punishable when he/she is acting with the consensus of the person who is validly entitled to such right”.

Moreover, in most Countries, and also in our own, it does not exist to date legislation prohibiting citizens to travel abroad to purchase organs from living donors in Countries where this practice is not considered illegal. The example of Germany⁸⁵ is to be followed, with the insertion of an extraterritoriality clause prohibiting citizens to purchase organs anywhere in the world, even in those non-European Countries where the trade in organs is legal⁸⁶. This is in consideration that this type of commercial transaction between fully capable and consenting adults, even though very different from the use of violence, fraud, threats or abduction, aimed at the procurement of organs, still poses strong moral and legal problematicity also for many of the reasons described above.

However, whether the legislator do not deem necessary the establishment of a clause of this kind, he must at least try to provide controls on the method of implementation of organ transplants carried out on the citizen outside his/her own borders, so as to discourage the temptation to travel abroad to obtain an organ by payment.

c) Other actors in this human tragedy, both moral and social, are the donors themselves, generally indicated as victims as they are desperate individuals, in highly vulnerable situations due to the economic status and the lack of prospects, lured by mediators. We can frequently read of a “colonised” population. By searching on the internet or specialised web it is easy to find “body for sale” (“kidney for sale”, “portion of human liver for sale”, “lung for sale”) and the doors of an increasingly expanding business burst open. In all parts of the world, especially in poor countries the spectrum of potential sellers is extremely wide and it is, above all, continuously and alarmingly in expansion.

⁸⁵ Gesetz über die Spende, Entnahme und Übertragung von Organen und Geweben, Abschnitt 7 Straf- und Bußgeldvorschriften, §§ 18 Organ- und Gewebelhandeln-19 Weitere Strafvorschriften, 1997. And the Greek Government in 2003 subjected to the attention of the Council of the European Union a proposal for the prevention and repression of trafficking in human organs and tissue making it punishable as a criminal offense for all those involved in transplant tourism, including patients / clients who paid to receive the organ. The Spanish penal code has provided from November 2010 with Article 156bis that whoever receives an organ, aware of its being obtained by illicit trafficking, is punishable with a period of imprisonment from six to ten years.

⁸⁶ As in our penal code, Art. 604 provides for the offense committed abroad by an Italian citizen.

Even in cases of personal initiative, the principle that organs can only be given as a gift, a gratuitous act to save or improve the lives of others must be reaffirmed and defended. Faced with these individuals criminal penalties do not, however, seem to be an appropriate and proportionate instrument, taking into account their particular conditions of vulnerability, that call to mind their economic hardship or that of their family members.

d) As regards prevention, it must be considered important to ensure social assistance, and a *welfare* system which are attentive to meeting the basic needs of the population. To both categories (potential donors and beneficiaries), there should be directed a strong and effective campaign to raise awareness, and to educate to try to make individuals gain awareness of the illicitness of the act, to create a collective consciousness about the consequences of the removal operations and the fundamental rights recognised in order to protect every human person. To make it clear to those who relinquish their body parts that they deprive themselves not only of these, but they endanger their own health, their lives and probably even the one of the buyers. To reiterate that the organ trade is not simply the result of the law of supply and demand in which everyone has an advantage: those who buy, recuperate their health, those who sell, obtain money to improve the necessities of life. Even those who maintain a vision of being owner of the body should not forget that the claim to that right meets well-defined limits within international documents and legal systems and to ask the law to allow negotiation of a fair price for a kidney is contrary to everything that contract theory represents (a free and conscious will is often lacking, also lacking is the object given that organs are not legitimate consumer goods). It is also possible to ask ourselves, “If those who live in conditions of social insecurity and economic neglect on the outskirts of the new world order really are “owners” of their body”⁸⁷.

The buyer must be conscious of the fact that whoever sells an organ in clandestine conditions is likely to reduce their life in terms of duration and that statistics show that before long the person will be in worse than average conditions of poverty. In addition, the buyer should also be aware that in many parts of the world these sellers, who are often young, have to face the

⁸⁷ N. Scheper-Hughes, *Il traffico di organi*, cit., p. 35.

mockery and ostracism of the social environment surrounding them⁸⁸. Lastly, as the surgeon Ignazio Marino writes, attention should be drawn from the donors/beneficiaries, to the fact “that if a surgeon is so unscrupulous to perform a transplant in full lawlessness and in contempt of the fundamental rules of ethics and deontology, in all likelihood he will not be very meticulous in verifying the compatibility of the donor or other clinical aspects related to this delicate operation, because his interest is purely economical, and the health of the person who ends up in the operating theatre is certainly not close at heart⁸⁹”. And, we might add, even after surgery.

e) Pivotal to the operations of transplantation of illegally obtained organs is the organisation which supports the operation: from the illegal procurement of the organ and recruitment of the recipient patient, to the guarantee of health treatment and the necessary transplantation procedures. Solicitation must be regarded as a criminal offense, when committed intentionally, by health care professionals and other individuals (intermediaries/brokers) in order to obtain organs outside the national transplant system, as well as offers of financial gain or comparable advantage to potential donors.

Also to be considered a criminal offense, when committed intentionally, is the preparation, preservation, storage, transportation, transfer, receipt, import and export of organs taken in the circumstances described in paragraph 3a, considering that all these activities are essential stages in human organ trafficking.

In reference to the gravity of the violations linked to human organ trafficking it is appropriate to include the responsibility of commercial companies, public facilities and organisations that may be involved in cases of criminal action committed by any person having the power of management, representation and control inside them. The responsibility of these bodies does not exclude the personal responsibility of the individuals that belong to it.

In all these different situations policies of deterrence must play a significant part, by providing mechanisms focused on increasing the risks and diffi-

⁸⁸ N. Scheper-Hughes, *Un segreto di dominio pubblico*, VV.AA., *Pezzi di ricambio*, Feltrinelli, Milan 2010, pp. 40 ff.

⁸⁹ I. Marino, *Un atto di amore*, in VV.AA., *Pezzi di ricambio*, cit., p. 152.

culties to carry out the illicit act. Above all increasing the risk means to jeopardize not only the personal assets and/or the personal freedom of surgeons, nurses, technicians, etc., through criminal sanctions but also to affect their professional reputation. As regards this last aspect deontological codes may have an important role in providing for strict penalties for offenders in this sector.

f) The legislator in counteracting these practices should include a ban on all types of advertising which encourage contacts with intermediaries/*brokers*. It is well known that clandestine trafficking relies heavily on websites which connect the donor-organisation-buyer and the net becomes the place for an exchange of information and for globalised negotiation. The control, monitoring and censorship of suspicious websites and of paper mass media is therefore required in order to thwart appealing propaganda and increase the difficulties for the seller to come into contact with criminal organisations.

For this purpose it would be useful to set up research groups specialised in the examination of internet exploitation and virtual traps, which could act as a deterrent for the online publication of advertisements by the merchants of organs.

g) Given the potentially serious consequences of the trafficking of human organs for the mental and physical health of the donors, the Committee sees a need for specific protection of these people. In particular it is deemed necessary that the victims of this market should be kept up to date regarding the state of progress of their files by the competent authorities and that they should be given the opportunity, in accordance with the domestic law of States, to be heard and to receive adequate protection when called upon to provide evidence⁹⁰.

⁹⁰ As regards the system of penalties and its application valid references on an international and European level can be supplied by the various Conventions set out in note 5. At the national level, in addition to the existing specific regulations in the field of organ removal and transplantation: *Provisions against sexual abuse* (Law 66/1966); *Provisions against the exploitation of child prostitution, pornography and sex tourism as new forms of slavery* (Law 269/1998); *Measures against trafficking in persons and slavery* (L.228/2003) *Provisions relating to the fight against sexual exploitation of children and child pornography also through the internet* (Law 38/2006); *Ratification and implementation of the Convention and the Protocols of the United Nations Convention against transnational organized crime* (L. 16 March 2006, No. 146).

An additional commitment is to deter the transition from “victim” to “victimiser”. Statistical data show that the brokers are commonly and frequently former sellers of their organs, recruited into the ranks of the mediators by being invited to establish a *partnership* in business and also through the promise of financial gain. This facilitated passage from the precarious conditions in which the donors find themselves, which, as already mentioned, the alienation of an organ is not a solution to their problems. The “intermediaries of the intermediaries” often have within the same social communities more ease in finding potential donors. Blocking this chain of assignments undoubtedly weakens the action of the traffickers, who in this way lose many of their affiliates. It is a feasible method of prevention and gives wide diffusion and prominence to the national and international penalties foreseen for brokers, and thereby increases the risks and costs of conduction of mediation.

h) The Committee also emphasises the importance of international co-operation. A system of effective counteraction to a dynamic crime that involves the territory of several States cannot be based only on state regulations, but it must be able to rely on judicial and political collaboration as well as the collaboration of the police between the countries concerned. As in other situations of transnational organised crime (take for example narcotrafficking or crimes of pedophilia) collaboration develops from the information given and exchanged between States from the need to centralise investigations and to establish databases devised for organ trafficking⁹¹.

Lastly, not to be overlooked is the need for progressive harmonisation of regulations in order to avoid that a lack or differentiated criminalisation of certain behaviour may prevent or make more difficult international cooperation between the various authorities.

⁹¹ In Europe there is the Eurojust one of the most incisive EU bodies in the field of European criminal judicial cooperation. Its establishment reflects the need to facilitate coordination between national authorities responsible for criminal prosecution and therefore provide their assistance in investigations relating to serious forms of international and organised crime involving the Member States. Joint investigation teams, in charge of conducting investigations in specific areas, have been established by the European Council at the *Convention on Mutual Assistance in Criminal Matters between the Member States of the European Union* (2000). They are composed by the judicial or police authorities of at least two Member States. Also operational are the *Joint investigative teams* of a global nature in order to facilitate the prosecution of criminal offenses and traffickers.

In order to improve the judicial response it is therefore essential to promote more congruous international conventions against trafficking *strictu sensu*, on condition that it may be individuated in its presuppositions and clarified as regards the conduct which characterises it, in short that defines it.

i) Lastly, considering that the practices that do not respect ethical principles are in part a consequence of the global shortage of organs for transplantation, our Country must commit to support, even financially, programs capable of increasing organ donation from both living and cadaver donors.

It is reiterated⁹², therefore, even on this occasion that the solution of the problem related to the sick person could open up health problems for the donor. In certain regulations this is precisely what is taken into account, when this act of generosity translates into a preference criterion on waiting lists in the event of a supervening need for an organ for the actual donor. An indication that our legislators, as well as others, should consider in order to mitigate the risk that the donor may incur a deadly disease caused by the very act that had as its aim the resolution of another person's pathology.

Recommendations

1. The Committee hopes for the realisation of the project of the Council of Europe to come to an agreement among the various member States with the aim to prevent, combat and criminalise the illegal trafficking of organs, it is a threat of global dimension, which endangers fundamental human rights.

2. The Committee believes that, although the idea of a system of regulation is difficult to achieve in the medical and social realities of many parts of the world, especially in poor countries, at least in Europe juridical, international and national regulations can be provided, with the introduction even of types of criminal offences, intended to define organ trafficking, to prevent it and to enforce the principle that the human body or its parts are not commercially tradeable.

⁹² NBC, *Kidney donation from a living donor to a stranger (so-called Samaritan donation)*, 2010.

3. It is desirable for States to work together on an international level to improve the practice of transplantation and organ donation and cooperate, in accordance with the relevant international instruments and their national laws, as far as possible, in order to carry out investigations regarding possible infringements committed on its territory and outside of it⁹³.

There should also be established, by agreement, with multilateral treaties based on the principle of double incrimination, the mutual recognition of the types of criminal offences, in order to ensure adequate collaboration between requesting Countries and the Countries in which the act was intentionally committed.

4. States should strengthen policies designed to encourage organ donation and it is also hoped that there will be cooperation on an international level to promote research into the field of regenerative medicine so that in future the achievement of such targets will make resorting to organ transplants no longer necessary.

Personal remark signed by Profs. Luisella Battaglia, Lorenzo d’Avack, Silvio Garattini, Vittorio Possenti, Rodolfo Proietti and Lucetta Scaraffia

The Opinion recommends the development of an international juridical instrument with the aim and purpose to prevent and combat organ trafficking, to criminalise such acts and protect the rights of the victims of these offenses.

The members of the Committee have come to agree on a number of measures to protect the victims and to provide for a criminal offense for acts that characterise and complete the trafficking of human organs.

However, particularly delicate seems the position of the doctor in the Country of origin, assigned with the duty to provide therapy and assistance, when a request is made by the patient-buyer who has acted in clandestinity.

⁹³ In this context it is appropriate to refer to the *European Convention on Extradition* (ETS No. 24/1957) and the *Additional Protocol to the European Convention on Extradition* (ETS No. 86/1979); to the *European Convention on Mutual Assistance in Criminal Matters* (ETS No.30/1959); the *European Convention on the Transfer of sentenced Persons* (ETS No. 112/1983) and the *Council of Europe Convention on laundering, Search, Seizure and Confiscation of the proceeds of crime and financing of Terrorism* (ETS No.198/2008).

Notwithstanding the obligation of the doctor to provide treatment, one could also consider the obligation to give notice of the illegal activity to the competent judicial authorities in order to launch an investigation.

The NBC, in discussing the problem, while requiring the supervision and responsibility on the part of the health authorities of each Country to ensure transparency and security, has decided not to address the issue regarding the obligation to report the event by the doctor or medical facility. The reasons for this choice are twofold: the appeal to classical medical ethics based on the Hippocratic tradition with its conception of the responsibility of the doctor toward the patient ‘to the best of his ability and judgment’, on the one side. On the other side of the coin, there is the concern that the patient, fearing sanctions, remains in the situation of clandestinity consequently possibly worsening his health.

These arguments, although reasonable, do not include other values that are no less important and ethically respectable, full of public service values, which require specific information useful to the fulfilment of goals nevertheless provided for by law and subject to the control of public security. Above all they do not take into account the fact that this would be one of the few ways available to us to learn about the illegal market in human organs. The ethical obligation to professional confidentiality and the privacy of the patient⁹⁴, moreover, for doctors could mean that they have to acquiesce to those committing an offense that is considered a crime against humanity, and “consequently become complicit as they are conscious of the commercial transaction”⁹⁵. Especially since there is a very clear difference in treatment between donor and receiver: while the former is usually left to himself somewhere in the world the latter is monitored and protected by the same doctors that he was receiving treatment from before the illegal transplant.

Even taking into account privacy and professional confidentiality, it can be assumed that a doctor - in the face of conflicting values, both ethical

⁹⁴ For the Deontological Code of physicians, Art. 9 et seq. and the Penal Code Art. 622. However, the law is inclined to believe that even though the doctor is committed to confidentiality, criminal effects occur only for revelations capable of real harm to the patient (undue damage), a situation which would not be present in the event the doctor becomes aware of an offense committed by the patient himself.

⁹⁵ I. Marino, *Un atto di amore*, in *Pezzi di ricambio*, edited by G. Mondadori, Milan 2010, pp. 151-152.

and juridical - should in any case be free to decide according to the best of his ability and judgment, reserving the ethical obligation regarding the provision of care in situations of need in order to always ensure treatment.

Presidenza del Consiglio dei Ministri



**INTENSIVE CARE UNIT “OPEN”
TO FAMILY VISITS**

19 July 2013

Presentation

The Opinion deals with a particular aspect of healthcare organisation, that of *visiting policies* (accompaniment and family visits) in the ICU: an application of the principle of respect of the person in healthcare treatments (Article 32, para.2) that is not always adequately considered. This principle involves taking charge of the patient, not only as an isolated individual and as a mere body to be treated, but as a person with meaningful relationships; which, the patient should not forcibly be deprived of, so as not to add the weight of loneliness (sense of segregation and separation) to the already serious condition of illness. In addition, the presence of loved ones, can be seen as an application of the principle of protection of autonomy, both because it satisfies a fundamental requirement of the patient according to his own instructions and because the patient receives support from his loved ones accompanying him during the stay in the ICU. *Last but not least*, given that, by doing so there is also an improvement in the same quality of the medical care, the model of the open ICU is to be recommended even for reasons of improved efficiency of the safeguarding of health. The ethical dimension of the problem is in accord with that of medical efficiency.

Numerous data, in fact, suggest that promoting access to the ICU for family members and visitors, not only does not constitute a danger for patients, but rather it is beneficial both for them and their families. In particular the “opening” of the ICU does not cause an increase in infections in patients, while statistically there is a significant decrease in both cardiovascular complications as well as *anxiety scores*; in addition, patients have hormonal indices of stress that are significantly lower. A further positive effect is represented by the clear reduction of anxiety in family members. For example, mothers of hospitalised children in an “open” ICU have stress indices that are lower than those with children in an ICU with “limited access”.

The Opinion makes clear, however, that an “open” ICU in no way means an ICU without rules, and it is therefore necessary to draw up guidelines which allow for organising the opening so as to safeguard the other values at stake (such as, security, order in the hospital, hygiene, privacy, confidentiality, intimacy). Therefore the Opinion also highlights the problem of the rules of behaviour which the visitors themselves must comply with; behaving respectfully towards people and places, in order to maintain orderly and advantageous access to hospitals and intensive care in particular.

The Opinion concludes by recommending promotion of the right of patients admitted to ICUs to have their families or loved ones close to them in accordance with their instructions. In order to achieve this general objective, ICUs must adapt their organisation and visiting policies to the model of the “open” ICU.

The Opinion has been drawn up by Prof. Andrea Nicolussi. In the drafting of the Opinion, Prof. Nicolussi primarily made use of the consultation and extensive written contributions of Dr. Alberto Giannini, who has worked for years on both the theoretical elaboration as well as practical experience in the development of the organisational model of the open ICU. Prof. Rodolfo Proietti, a member of the expert Committee in this field, carried out general scientific and technical supervision. Other written contributions were received from Prof. Antonio Da Re and the late Prof. Adriano Bompiani, just a few days before his death. The Opinion also takes into account the suggestions of Profs. Salvatore Amato, Francesco D’Agostino, Lorenzo d’Avack, Riccardo Di Segni, Silvio Garattini, Marianna Gensabella, Laura Guidoni, Laura Palazzani and Monica Toraldo di Francia.

In the plenary session of the 19th July 2013, the Opinion was approved unanimously by those present, Profs. Salvatore Amato, Luisella Battaglia, Stefano Canestrari, Francesco D’Agostino, Lorenzo d’Avack, Antonio Da Re, Riccardo Di Segni, Carlo Flamigni, Romano Forleo, Silvio Garattini, Marianna Gensabella, Laura Guidoni, Demetrio Neri, Andrea Nicolussi, Laura Palazzani, Rodolfo Proietti, Giancarlo Umani Ronchi, Monica Toraldo di Francia and Grazia Zuffa. Profs. Cinzia Caporale and Assuntina Morresi were not present at the time of voting and subsequently approved the Opinion.

The President
Prof. Francesco Paolo Casavola

Introduction

The National Bioethics Committee in this Opinion pays attention to a particular aspect of healthcare organisation - that of the presence of family members and visitors in the intensive care unit - which not only has implications on the quality of care, but also involves elements of particular importance even as regards specific bioethical reflection.

The issue pertains to the more general question of the humanisation of care, of which accompaniment and visits to hospitalised people constitute a fundamental part. It can be seen as a time of development of the tendency to promote a greater respect for the individual in treatment and healthcare facilities, also consistent with a conception conducive to a broader protection of health, inclusive of the material and social conditions most suitable for the well-being of the person. This new orientation, above all starting from the second half of the twentieth Century, led to introduce significant changes in the healthcare organisation. Even in Italy, notwithstanding frequent delays, the regional inequalities and organisational difficulties often reported in our Country, some progress has been made, particularly since Law No. 833 of 23rd December 1978. By means of this a general framework for the development of Italian healthcare has begun to be delineated, establishing in an organic manner the different sectors and introducing the collaboration of the various requests of civil society that have emerged in the meantime: take for example the “movement for the protection of the rights of the sick” and the “movement for the so-called humanisation of hospitals” to the training and legal recognition of voluntary assistance in its various forms, these contributions were institutionally recognised and received intrahospital representation, contributing to modernising hospital management.

In this context, enhanced by a renewed culture of the protection of health, sensitive also to the recommendations from the psychology and sociology of health, the then new requirements were able to become relevant and were initially met, even thanks to cultural stimulus and the collaboration of universities. One need only to recall psychological assistance by suitably trained workers, the preparatory courses for pregnancy and childbirth which also included the presence (if requested by the parturient) of the father in the delivery room, “*rooming in*” in order to facilitate initial “maternal-neonatal attachment”, the possibility for mothers to stay next to sick children even during the night in pediatric wards - when recommended, longer vis-

iting times by family members to patients and, more recently, the discipline of palliative care. These are examples of a progressive modification of the approach that was in the past dominant in hospitals - characterised by a “directorial and paternalistic” attitude and by an objectivising conception of the hospitalised person, reductively considered merely as a body, the object of treatment - towards a greater openness to human needs and better co-operation with families which even in Italy is gradually being achieved, despite persisting difficulties not only of an economic nature.

Indisputably, much is still to be done to make health facilities and the training of personnel better equipped to promote full respect of the human person as patient, making possible, as appropriate, the presence of loved ones, and so avoid imposing, on those who are already in a serious condition of discomfort, an artificial separation from their relational life. In this broader framework, this Opinion of the NBC focuses on the particularly sensitive sector of hospital stays in intensive care and resuscitation units.

Precisely from this specific point of view, it may be appropriate to recall that more than ten years have gone by since Hilmar Burchardi, then president of the *European Society of Intensive Care Medicine* (ESICM), wrote in an editorial in the official journal of ESICM that “*it is time to recognise that the intensive care unit should be a place where humanity is given the highest priority. It’s time to open those intensive care units that are still closed*”. The time interval that has elapsed since then has certainly led to the changes in direction desired by Burchardi, but the “openness” of Intensive Care (ICU) even if it is no longer a “dream” is certainly still far from being completely a “reality”.

The international literature in the field provides a mixed picture regarding *visiting policies* (i.e. the rules that govern the presence of family members and visitors) in the ICU. The most recent data indicate that the percentage of ICUs that do not place restrictions on visiting over 24 hours is 70% in Sweden, 32% in the U.S., 23% in the UK, 14% in Holland, 7% in France and 3.3% in Belgium.

According to the data of two recent studies, Italian ICUs maintain on the whole one of the most restrictive *visiting policies*. However, over the last five years in Italy there has been a small but not negligible change: the median of daily visiting hours has essentially doubled (from 1 to 2 hours) and there was a real increase (from 0.4-2%) in the percentage of ICUs that allow

visiting over the entire 24 hours. However, in ICUs for adults, there are restrictions on both the number of visitors (92% of ICUs) and on the type of visitors (17% of the wards admit only close family members, 69% do not allow children to visit). In addition, a part of the ICUs do not change their rules regarding access for visitors neither if the patient is a child (9%) nor if the patient is dying (21%). Almost all of the ICUs impose the use of protective clothing (lab coat, shoe covers, mask, gloves). A particularly significant aspect is the fact that a quarter of ICUs for adults do not have a waiting room for family members.

As regards Italian pediatric ICUs, currently visiting hours are on average five per day. 12% of wards do not impose restrictions in the 24 hours on the presence of parents, while 59% do not allow the constant presence of a parent, not even during daylight hours. Lastly, one-third of pediatric ICUs, do not have a waiting room for family members.

In Italy even neonatal ICUs have, on the whole, rather restrictive visiting policies: only 30% of them, for example, allow entry to parents 24 hours a day (compared to 100% of Swedish, Danish and UK ICUs, or 71% of those in France).

1. Promoting visiting policies in the ICU

1.1. The reasons for a choice

For many doctors and nurses the expression “open” ICU is still a sort of oxymoron or, in practice, an unrealistic condition: noun and adjective would be opposed in an inescapable contradiction. This point of view is largely consistent with the origins of intensive care medicine. In fact, since their introduction less than fifty years ago and for many years afterwards, ICUs have been - in Italy as elsewhere - “closed” wards where access to family members and visitors were regarded unfavorably and, therefore, very limited. This separation of the patient from the people dear to him was motivated mainly by fears regarding the risk of infection, interference with patient care, increased stress for patients and their families, and breach of the confidentiality of information.

So, for many years the admission of a patient in the ICU has followed what has been described as the “principle of the revolving door”: when the patient entered, the family was sent out. The logic that one can see in these

consolidated behaviours can be traced to a technocratic-rationalist conception that tends to rigidly separate the places of different technical and work activities from those of family relations, while absolutising the good reasons relating to organisation, safety or hygiene. In this perspective, in fact, we tend to believe that, in terms of a strategic objective of primary importance such as the protection of the life and health of the patient, we can proceed to a sort of “kidnapping” of the patient. The reduction or abolition of contacts with the patient’s own world of meaningful relationships and affections would, in other terms, be the price to pay for having a significantly higher benefit, which is, precisely, the protection of life and health. Hence the lack of concern to make compatible with such an objective the maintaining of relationships, as far as possible, and therefore combine rather than separate, biological life and relational life.

However, on the basis of scientific evidence not only do certain reasons given for limiting visiting have no basis, indeed there are strong arguments in favour of increased access to the ICU by the patient’s family members. Current knowledge has shown that separation from loved ones is a significant cause of suffering for the patient admitted to the ICU and that, for the family, to be able to visit without excessive restrictions, represents one of the most important needs. In this regard, it is interesting to note that doctors and nurses greatly underestimate both the need of the patient to have their loved ones close to them as well as the need of the family to receive information and to be able to be near to the loved one (these needs, together with reassurance, support and comfort are those mostly manifested by the families of the patients of ICUs).

Considering more specifically the pediatric field, separation from parents has long been recognised as a major source of stress for hospitalised children. From the point of view of parents, as well as the uncertainty related to the child’s illness and its outcome, a significant cause of stress is the loss of their parental role. Being with the child, along with frequent and accurate information about his condition, represents the greatest need of parents and often their priority is not being constantly present at the child’s bedside, but rather the possibility of visiting the child when they can or wish to. *Mutatis mutandis*, the separation from loved ones is a serious limitation also for the elderly who often need the comfort and support of family members even to make decisions relating to health care treatments.

The separation from loved ones for the patient often becomes an additional and unjustified “price to pay” that is not related to the illness or to the serious event giving rise to admission to the ICU. Alongside the suffering of the patient there is, however, also that of members of the family, which often goes unrecognised or is not considered: symptoms of anxiety and depression, for example, have been detected respectively in 73% and 35% of family members. In addition, symptoms of post-traumatic stress compatible with a moderate to severe risk of post-traumatic stress disorder (PTSD) have been reported in 33% of family members. It is important to point out that the suffering of the family is neither a tardive event (i.e. associated only with prolonged hospitalisation) nor a transient one. Conversely, it begins early and may be persistent. Data in literature indicate that already 3-5 days after admission of the patient to the ICU a high percentage of family members have symptoms of traumatic stress (57%), anxiety (80%) and depression (70%). In addition 6-12 months after discharge, it is estimated that 27% of the parents of children admitted to a pediatric ICU is at high risk of PTSD (compared to 7% of the parents of children admitted to a ward). These and other studies have helped to define a precise framework, called *post-intensive care syndrome family* (PICS-F), constituted by a series of psychological complications occurring in the family members of a patient admitted to the ICU.

Numerous data suggest that promoting access to the ICU for family members and visitors not only does not constitute a danger for patients, but rather it is in fact beneficial both for them and for their families. In particular, the “opening” of the ICU does not cause an increase in infections in patients, while there is a statistically significant decrease in both cardiovascular complications and the *anxiety score*. Furthermore, patients present significantly lower hormonal stress indices. A further positive effect is represented by the sharp reduction in anxiety in family members. For example, mothers of children admitted in the “open” ICU have stress indices lower than the mothers of children in ICUs with “limited access”.

Lastly, the respect of secrecy (or confidentiality) of information, is not infringed by the presence of family members and visitors, but this may occur through incorrect methods of communication. In fact, it is both appropriate and essential when consulting family members and, in particular, when communicating clinical data, the submission of assessments of possible prognostic and therapeutic choices, to dedicate the necessary time, as well as to

apply the appropriate procedures and if possible, set aside a suitable place. The question of correct procedure also concerns the related topic of respect for the intimacy of patients, which however is an issue that regards all patients admitted to healthcare facilities in general.

1.2. Visits by children

Also children visiting family members patients in the ICU, represent, under certain conditions, a positive event[36]. In this regard, a Swedish national multicentric study found that all the ICUs involved had a favorable *policy* regarding visits by children to adult patients, even though 34% of the wards actually had some restrictions.

It should also be taken into account that there are no real reasons to systematically discourage the visits of brothers and sisters to children hospitalised in the ICU: the presence of a brother or sister can have a positive and reassuring effect on the patient. Apart from certain specific exceptions (such as when the visitor has an ongoing contagious disease), if the child is properly prepared and supported by the family (and other “strong” educational contexts, such as school) to be able to pay a visit to a brother or to a sick sister helps to dispel fantasies of loss or death, and gives reassurance regarding the constant attention of the parents.

1.3. The presence of family members during procedures

This issue has been particularly investigated in the pediatric field and has been recently reviewed, almost all parents want to be able to choose whether to stay with the child during invasive procedures and resuscitation, and those who made this choice would do the same thing again in future. Parents can soothe or emotionally support the child and help the team. In addition, reduction of anxiety and aid in the process of mourning are two of the main benefits for parents who have had the opportunity to be present during procedures or resuscitation.

Although the presence of family members during resuscitation procedures has been the subject of recommendations and have shown, on the whole, to be beneficial for family members (in terms of reduced incidence recorded in time of symptoms related to PTSD, anxiety, and depression), nevertheless it is not unanimously considered as positive and continues to cause some concern among doctors and nurses.

In Italian pediatric ICUs a clear trend has been detected towards limiting the presence of parents during procedures (including those of ordinary *nursing*) and resuscitation manoeuvres, while no data are available on ICUs for adults. In 38% of pediatric ICUs parents are not allowed to attend the normal nursing procedures such as endotracheal suctioning. In the case of invasive procedures such as the placement of a central venous catheter and in the case of cardio-pulmonary resuscitation, the presence of parents is allowed respectively in only 3% and 9% of ICUs.

2. The “open” Intensive Care Unit

2.1. Ethical aspects

Though in general there is essentially no solid scientific basis for impeding or unnecessarily restricting the access of family members and visitors to the ICU, there are good reasons both ethically and clinically, for making it possible and encouraging it. Only serious risks to public health - such as, particularly serious epidemic phases - may exceptionally justify impeding visits.

A first element to be considered from the point of view of ethics is constituted by the principle of respect for the individual as patient in the medical treatments, foreseen in art. 32 para.2. The individual must be respected in his entirety and therefore in relation with others, without imposing unjustifiably the condition of separation at the very moment in which he is subjected to medical treatment. The places of care, and medical treatments should therefore be arranged so as to separate the individual the least possible from his life-worlds, favouring the moments of continuity with the family and the social experiences of the persons involved. In this way, the autonomy of the patient is also respected, being supported and strengthened by the presence and accompaniment of loved ones, while unnecessarily enforced solitude exacerbates the already difficult condition of illness and constriction in the ICU. The decisional autonomy of the patient is also respected at least when the patient is able to express his own will regarding the presence of the persons close to him, with whom to maintain meaningful relationships. In fact, the patient - when circumstances permit - should have the opportunity to state which persons are particularly significant to him and therefore those who he wishes to have next to him during the difficult

time of illness. This, moreover, is one of the main needs expressed by patients admitted to the ICU. Over the last decades the medical field has also developed a more mature sensibility towards the person as a whole, perceiving not only the physical-objective dimension, but also the subjective one, bringing awareness to the need to respect this dimension also and especially in the sick person by virtue of his condition of frailty and dependence. Therefore, during the period of illness not only should implementation of the rights of the sick person as an individual be supported and made effective, but - even if altered and reduced - the patient's significant emotional relationships should not be mortified let alone abolished.

Moreover, from the practical point of view, a substantial percentage of the admissions to the ICU is not caused by acute or sudden events, but is instead scheduled (major surgery, transplants) or it is a predictable stage in the evolution of chronic diseases (cancer, heart, respiratory, neurological diseases etc.). There are therefore numerous possibilities to consult with patients regarding their wishes, so that they can decide in advance those whose presence is important to them. The treating physician should therefore feel the responsibility to consult patients in good time on this issue. Even later, during hospitalisation in the ICU, patients should always be able to exercise the right to determine and request that the presence of significant individuals within their familiar and emotional world be permitted.

Of course, those unable to express their will and children must also be respected in their need to maintain relations with family members. Respect for the human person transcends the ability to express one's wishes and will.

A further consideration concerns the ethical principles of *beneficence* and *non-maleficence*. On the basis of current scientific knowledge and extensive practice, the presence of loved ones next to the patient does not in any way constitute a "threat" to the patient, on the contrary, it is a positive action capable of producing beneficial effects in a situation which is particularly arduous, both for the patient and family members. In ethical terms, it is therefore not justifiable - except in exceptional cases - to renounce carrying positive action in this regard, able to offer benefits to the patient. The protection of health, in other words, does not necessarily require the sacrificing of relational life, not even in ICUs.

Although doctors and nurses have no formal specific obligation towards family members, but only towards the patient, many studies and recommen-

dations today acknowledge the opportunity for the team of doctors and nurses in the ICU to take care not only of the patient, but, in a broad sense, also of his family. First of all, consideration shown to family members is, in most cases, deemed as consideration towards the patient himself who has not severed family ties, eliminating, so to speak, life's experiences. And such attention, considering him as a person with his own experiences and significant relationships has as a result an improvement in care itself. In addition, wherever this can be achieved while respecting the autonomy of the patient, the consideration of his family relations has beneficial effects also as concerns the family members themselves. This approach has led to the elaboration of the initial model of the "patient-centered" ICU and, therefore, of the "family-centered" ICU (*patient centered Intensive Care Unit* and *family centered Intensive Care Unit*).

Philosophical reflection has pointed out that the ability to recognise *the face of the other* generates in the interlocutor responsibility *towards* him and relationship *to* him. It is possible to "translate" these terms - *responsibility and relationship* - even in the complex world of intensive care medicine, generating new action and language. It is in this perspective that the choice of "open" ICUs also makes sense on an intrinsically ethical level, and it becomes necessary precisely because it not only responds more fully to the needs of the other, but also because it expresses more adequately consideration and respect for the life and well-being of the other.

2.2. Field experience

With the understanding that fostering an extension of visiting hours has beneficial effects both for the patient and family members, the need to "open" ICUs has been highlighted and recommended on several occasions and in an authoritative way. However, from the framework outlined above we can say that in many Countries, and in Italy in particular, there still is not full consciousness that the presence of loved ones is beneficial to the patient and that in the context of intensive care the family actually constitutes a resource more than a hindrance.

The experience of wards that have already liberalised their visiting policies provides some interesting information. A French study, for example, has highlighted three aspects. First, the average time for visiting is about two hours a day and the majority of family visits are concentrated mostly in

the afternoon and in the evening (therefore not causing any “invasion” of the ICU). This probably happens because relatives even during this particular period of difficulty and suffering, are still forced to deal with all the commitments imposed by normal working and family life - and at times are forced to perform a balancing act. Secondly, doctors and nurses have recognised that liberalisation of visiting has not compromised patient care (even though a certain uneasiness on the nurses’ part stemming from fear of interference with care has been noted). Finally, the majority of family members report that being “open” over 24 hours has eased their anxiety. A recent Italian study also found that the majority of doctors and nurses of ICUs positively evaluate this “openness” in the ward and, on the whole, they have retained this opinion a year after the *policy* change.

2.3. Not only a question of time

The promotion of *visiting policies*, however, represents only one aspect of a more complex issue and it is useful to propose a change of perspective. Creating “open” ICUs is not just a question of visiting times: we need to consider them as “open” also on the physical and relational level. Pertaining to the *physical level* are all the barriers that, for different reasons, are proposed or imposed on the visitor, such as the absence of physical contact with the patient and the use of protective clothing (whose effectiveness in terms of infection control is called into question). Pertaining to the *relational level* instead, are all the expressions, of varying intensity, of fragmented, compressed or ineffective communication between the three elements that make up the vertices of the particular “relational triangle” that is established in the ICU: the patient, the treatment team and the family. If we consider these aspects, an “open” ICU may be defined as *the unit of intensive care where one of the objectives of the team is a rational reduction or abolition of all restrictions that are not justifiably necessary on the temporal, physical and relational level.*

Seeing with their own eyes the work carried out in the ICU helps to reassure family members, reinforcing in them the belief that their loved ones are cared for in a thoughtful and constant manner. In addition, “open” access contributes to better communication with doctors and nurses, and considerably increases trust and appreciation towards the team. An expression of this may be the data recorded by an American study which showed that lib-

eralisation of *visiting policies* in the ICU has improved the perception of patients and their families regarding the quality of care, and has also led to a reduction in litigation.

2.4. A new language

The work in the ICU and the efforts to create ICUs focused on the patient and his family can be enriched with new words and actions, through this “openness”. For example, the words *reception and hospitality* are very rich and suggestive expressions to indicate the modality of relation with the other, even in a hospital setting. They can certainly be “inflected” in the specific reality of the ICU and transformed into concrete gestures and coherent behaviours.

An “open” ICU therefore offers the possibility to create new actions and language full of humanity. A first example concerns the body: touching the body of the patient, caressing, feeding it a little, and so on, are gestures of enormous value both in relational and therapeutic terms. An effort must be made to create the necessary conditions to make this possible (with all due care), but it must be clear that the patient’s body is not necessarily “expropriated” and inaccessible to his loved ones.

This society does not want to “see death”, it censures and conceals it. However, no branch of medicine more than that of intensive care makes clear how medicine is in fact governed by limitations. The doctors and nurses of the ICU experience first-hand the extent of these limits and deal with *death* almost on a daily basis. In light of the above considerations on the significance of the “open ICU”, even death can be approached differently, with language and gestures different from the usual ones. In fact, we are generally accustomed to the act of *delivering the body* after death, but instead we can create the conditions for *the person to be accompanied* during the time of death. Provided that circumstances allow, and death is not an acute and unexpected event, it is important to allow family members to stay with their loved one even in the final stages of his life, staying close to him, caressing him (or if it is a child holding him in their arms), talking to him with the gestures and vocabulary of their special intimacy. These are difficult and complex stages that, however, are enormously important. Moreover, all these farewell gestures are the first step in a proper grief process.

2.5. Facing the difficulties. An “open” ICU does not mean an ICU without rules

The “open” ICU is therefore able to offer more complete and appropriate answers to some of the needs of patients and their families. However, it would be wrong to minimise the difficulties or inconvenience related to an innovative choice of this kind. These are mostly related to habits and aspects of a “cultural” nature, involving the medical and nursing team as much as the family members of the patients themselves.

An “open” ICU does not mean in any case an ICU “without rules”, and a regulation is useful and necessary organizing the opening hours in order to safeguard also the other values at stake. Family members and visitors should therefore be requested not only to give close attention to all the patients in the ward, but also to comply with certain rules of hygiene (e.g. washing hands before and after the visit), security (e.g. avoid touching equipment or infusion lines) and management (e.g. going out during emergency operations). One must also take into account the concerns put forward by some doctors concerning the risk that relatives may take outside the most dangerous and selected germs by antibiotics. Even from this point of view the most appropriate measures should be adopted. Furthermore, one should also take into account the patients’ right to respect for their privateness and their privacy by visitors who are strangers to them. It is a problem that actually relates to hospitals in general, but which carefully considered even in reference to the specificity represented by the ICU should provide rules, routes and other forms of protection to safeguard patients even in regard of their condition of frailty. This is one aspect, however, which is connected to the need, certainly not confined to the ICU, to introduce and make fully operative a charter of duties of the visitor, distinguishing between stable visitors and occasional visitors, in order to avoid confusion, impediments, and lack of respect for patients and the people who work in the healthcare facility in general. It is also important to ensure the team of doctors and nurses their own time and spaces, allowing them freedom of communication, with full respect for confidentiality and some essential pause that is not fragmented by interruptions.

Finally, one should not negate or underestimate the difficulties that the team of the ICU (particularly the nurses) might encounter with the opening of the unit, difficulties connected basically to a different way of relating to

family members and to the effort of learning to work when observed by family members. Doctors and nurses must therefore be adequately prepared and supported in the various stages of realisation of the “open” ICU model.

Conclusions and recommendations

The NBC believes, therefore, that the organisational model defined above as the “open” ICU:

a) fully expresses the principle of respect for persons in health care treatments orienting health care organisation according to the primacy of the dignity and rights of the person, even in a time of particular fragility and dependency as represented by serious illness requiring intensive care;

b) is a useful and effective choice to respond to some important needs of the patient and his family.

On the basis of these considerations, the NBC puts forward the following recommendations:

1) the organisation of ICUs should be geared to promoting the right of patients admitted to the ICU to have present beside them the family members or loved ones who they consider as significant figures;

2) family members - and especially the parents of hospitalised children and close relatives of the elderly - and in general persons specified by the patient must be able to have the opportunity to stay close to the patient in the ICU;

3) patients who are able to express their will must therefore be consulted as to the persons they want to remain beside them, while in the case of patients currently incapable of expressing their wishes, their previous “advance directives for treatment”⁹⁶ must be taken into account, and of course even the choice of the patient not to receive any visits must be respected;

4) ICUs must gradually adapt, i.e. in relation to the compatibility with existing facilities and currently existing equipment, and taking into account the other values at stake (e.g. Privacy and intimacy), their organisation and their *visiting policies* to the “open” ICU model;

⁹⁶ As regards advance directives for treatment, see the NBC Opinion, *Advanced treatment statements* dated 18th December 2003.

5) the doctors and nurses of ICUs should receive adequate and updated training regarding the precautions to safeguard hygiene, safety and orderly conduct of visits, communication, conflict management, the ability to recognise and address the needs of family members as well as their anxiety and stress;

6) National and regional plans for the construction of health facilities must include spaces that are adequately equipped to foster the presence of the families of patients and of visitors;

7) the Health Administration, in its various aspects, must undertake to promote and support implementation of the “open” ICU model.

Presidenza del Consiglio dei Ministri



**CONJOINED TWINS AND SURGICAL SEPARATION:
BIOETHICAL ASPECTS**

19 July 2013

Presentation

In this Opinion the Committee dealt with a delicate, even though not frequent issue, which calls for deep bioethical reflection that might be of guidance in complex decisions at clinical level.

Even though recognising the complexity and variability of the single cases, the Committee tackles two main situations, with reference to new born babies/minors.

A first condition is the one in which the life of the twins is not in immediate danger, while the surgical separation, although technically possible, is highly risky for the life of one or both twins. The document highlights two principle lines of thought: the line of those who, referring to the value of human life, consider that to the extent to which an operation is not necessary and is disproportionate, it is not ethically justified; the line of those who on the basis of various arguments consider surgical separation ethically licit even when the risk is high, as long as it creates even slender hopes of success.

A second condition is that in which, on the basis of an objective clinical evaluation supported by empirical data, the certainty is manifested of the imminent and serious threat to the lives of both twins. Different lines of thought are to be found in this context too: on the basis of different arguments some consider that the parents' choice of not intervening is justifiable, also in contrast with the doctor's clinical opinion; the wide majority of the Committee considers that before an appreciable and reasonable forecast of a slender chance of survival for one of the twins, surgical separation is dutiful, invoking the protection of life.

In the conclusions the document outlines a number of guidelines as a reference context to foster ethically complex decisions at clinical level, which refer to the promotion of research and the professional training of the healthcare operators, the importance of adequate information and psychological support for the parents, the duty not to intervene in the event that experimental persistence occurs, the role of the ethical committee and the duty to maintain confidentiality.

The Committee maintains that in the case of adults, the wish of the twins must be considered identical to that of any other competent adult, even with reference to the choice of undergoing experimental treatment or of refusing therapy.

The Opinion was coordinated and drafted by Profs. Salvatore Amato, Lorenzo d'Avack, Laura Palazzani, with substantial contributions from Profs. Bruno Dallapiccola, Adriano Bompiani, Stefano Canestrari, Riccardo Di Segni. Profs. Antonio Da Re, Francesco D'Agostino, Marianna Gensabella, Assuntina Morresi, Demetrio Neri, Monica Toraldo di Francia took part in the working group and contributed to the debate.

A precious contribution was given by the first-hand experience of Profs.: Bruno Dallapiccola (Scientific Director of the Paediatric Hospital Bambino Gesù of Rome and member of the National Bioethics Committee), Pierpaolo Mastroiacovo (President of the Ethics Committee of the Paediatric Hospital Bambino Gesù, Director of the "Central Office of the International Clearinghouse for Birth Defects Surveillance and Research" and "ICBD - Alessandra Lisi International Centre on Birth Defects and Prematurity", WHO Collaborating Centre), Pietro Bagolan (Director of the Department of Surgical Medical Neonatology of Bambino Gesù and member of the Ethics Committee of the Paediatric Hospital Bambino Gesù of Rome).

The Opinion was approved unanimously during the plenary session by Profs.: Luisella Battaglia, Stefano Canestrari, Bruno Dallapiccola, Antonio Da Re, Lorenzo d'Avack, Maria Luisa Di Pietro, Riccardo Di Segni, Romano Forleo, Silvio Garattini, Marianna Gensabella, Laura Guidoni, Assuntina Morresi, Andrea Nicolussi, Laura Palazzani, Monica Toraldo di Francia, Giancarlo Umani Ronchi, Grazia Zuffa. Profs.: Cinzia Caporale, Francesco D'Agostino, Carlo Flamigni, Demetrio Neri, Vittorio Possenti, Rodolfo Proietti, Lucetta Scaraffia expressed their approval at a later date.

The President
Prof. Francesco Paolo Casavola

1. Brief scientific description of the phenomenon

Definition

Conjoined⁹⁷ twins are united by one part or several parts of the body and may share apparatus and organs⁹⁸.

History

References to them exist in different cultures, from far-off ages. Numerous cases have been recorded (the first in England in around the XII century, in Venice in the XVI century, in Hungary and Bohemia in the XVIII century and in Siam in the XIX century) and scientifically analysed (the first was described in medical literature in Mexico in 1868). Many of them were considered as a ‘curiosity’ or a ‘monstrosity’⁹⁹ and were all too frequently used for shows in the past.

Etiology

The etiology is uncertain¹⁰⁰. There are two scientific theories explaining their origin with reference to an abnormal embryonic development: the *fusion theory* and the *fission theory*.

The fusion theory explains the conjunction of the twin birth making reference to the process of fusion, by means of which the two separate embryos partially fuse together. This theory does not explain the prevalent symmetrical conjunction of the twins (that is, always in the same part of the body or the so-called *mirror-image*), with the only exception of the phenomenon

⁹⁷ The terminology ‘Siamese twins’ derives from the Chang and Eng Bunker twins (1811-1874) from Siam (today Thailand). This is nevertheless a non-scientific term, even if widely used.

⁹⁸ O.M. Mutchinick et al., *Conjoined Twins: A Worldwide Collaborative Epidemiological Study of the International Clearinghouse for Birth Defects Surveillance and Research*, in “American Journal of Medical Genetics”, Part C (Seminars in Medical Genetics), 2011, 157, pp. 274-287. The article gives the most extensive study of the phenomenon in the context of worldwide multi-centric research.

⁹⁹ G.M. Gould, W.L. Pyle (eds.), *Anomalies and Curiosities of Medicine*, ch. V Major Terata, W. B. Saunders, Philadelphia, 1986, pp. 162-213.

¹⁰⁰ In ancient times and during the Middle Ages the birth of conjoined twins was said to be caused by: interventions of the devil, type of food, position of the woman during pregnancy.

¹⁰¹ It is the phenomenon by which only a partially formed baby can join itself at the same part, for example head/head, or at a different part of the other twin’s body.

of the parasitic twin¹⁰¹: the chance fusion could result in an asymmetrical conjunction.

The fission theory, which is the most substantiated today, explains the phenomenon as a late and incomplete scission of the zygote; after fertilisation, the embryo does not complete its division. Initially only one, the embryo undergoes a late separation around the 14th to 15th day following fertilisation and is not able to complete the separation of the two inner cell masses. Consequently, instead of producing two embryos that are distinct and independent in their parts, sharing a single placenta, it produces two partially conjoined embryos. A small percentage of identical twins presents a single *corion* (placenta) and a single *amnios*. This means that the division of the embryo took place after the 9th day. These embryos risk giving rise to conjoined twins¹⁰².

In the case of *conjoined twins* it is considered that the error in development occurs around the 14th to 15th day after fertilisation. This results in *monochorionic* and *monoamniotic* twins. The non completion of the separation of the precocious inner cell mass (*germ*) into two distinct embryos brings about the sharing of anatomical parts, organs, blood vessels etc., in a combination that can be extremely variable from case to case. These anatomical and structural differences not only classify the typology of the conjoined twins, but also affect their survival and the possibilities of successfully separating them surgically.

¹⁰² This is the thesis of Scott F. Gilbert, *Biologia dello sviluppo*, VIII, Bologna 2005, p. 333; M. Barbieri, P. Carinci, *Embriologia*, Editrice Ambrosiana, Milano, 2000. In about one third of the twins that are born, the derivation from one single fertilised egg is recognised, and it is therefore defined “*monozygotic*”. This definition is demonstrated by molecular tests, which characterise the same genome of *monozygotic* twins and the sharing of 50% of the genetic features in *dizygotic* twins. In twins with two separate placentas (so-called *bichorial*) the separation into two parts of the original blastomeres of the inner cell mass took place before the fourth day following fertilisation, the moment in which the trophoblast (layer of tissue that is the precursor of the placenta) has already been defined. In the most common cases in which *monozygotic twins* share the same placenta (so-called *monochorionic*), each of which is surrounded by its own *amnios* (*diamniotic*), the separation takes place before the formation of the *amnios*, that is between the 3rd and 8th day following fertilisation. In this case the twins are defined as *monochorionic diamniotic*. Much more rarely, even though the twins are completely separate, they are surrounded by a single *amnios* insofar as the separation took place between the 8th and 12th day. Owing to this characteristic they are defined as *monoamniotic monochorionic* twins. In each of these combinations, the twins are separate from each other.

In order to explain the formation of conjoined twins hypothetically, one can refer to a partial ‘splitting’ of the longitudinal primitive streak (cranial-caudal). If this splitting takes place towards what is destined to become the cephalic end of the embryo, it should lead to the duplication of some parts that originate from this end (for example two heads, two chests etc.); if instead, the splitting takes place in the opposite caudal direction, duplications of the parts collocated along this direction arise (for example, double intestine, double liver, double pelvis, etc.). If the phenomenon of the right or left lateralisation with respect to the primitive streak of the collation of some organs is added to this process, the general picture of the clinical presentation of the conjoined twins will be complicated by the coexistence of further anomalies.

Typologies

The various clinical presentations of conjoined twins have given rise to different classifications. The most widespread differentiates twins on the basis of the conjoined parts of the body and the shared organs (with the use of the Greek suffix ‘pagus’ that means ‘fixed’): *thoracopagus* twins, positioned one opposite the other and conjoined from the upper part of the thorax to the upper part of the abdomen; *cephalopagus* twins, joined from the upper part of the head to the navel, with two incomplete faces, two necks and the remaining parts of the body separate; *parapagus* twins, joined laterally, that generally share the pelvis, with heads and upper limbs separate and generally three legs; *omphalopagos* twins, conjoined at the level of the navel region and the low thorax, with a separate or conjoined heart; *craniopagus* twins, conjoined at the brain (meninges and superficial part of the brain) with trunk and distinct faces; *xylophagus* twins, that share a single sternum; *ischiopagus* twins, conjoined at the pelvis, genitals and anus.

Combinations of these defects are also possible (e.g. cephalo-thoracopagus or thoracopagus-omphalopagos). According to the type of conjunction it is technically possible or impossible to surgically separate the twins, who in many cases die a premature death.

There are also asymmetrical or unequal conjoined twins, incomplete twins ‘attached’ externally to a twin that can be defined complete: the ‘*vanishing* twin’ (known also as ‘foetal resorption’), is the foetus that belongs to a multiple pregnancy, who dies in utero and is partly or completely reab-

sorbed by the co-twin¹⁰³; ‘parasitic twins’ are formed when one twin begins to develop in the womb, but the co-twin does not separate completely and a twin takes on the main development at the expense of the other.

Unlike conjoined twins, one of the co-twins ceases to develop during pregnancy and takes on features that vary between the presence of vestigial structures and the presence of an almost completely formed twin. The twin that develops only partially is defined as parasitic, rather than conjoined, insofar as it is only partially formed and its development is entirely dependent on the functions of the complete co-twin. The independent twin is also defined as autosite¹⁰⁴.

Incidence

Conjoined twinning is a rare phenomenon and is also to be found in the animal world. In the literature very differing numbers are published, varying from 1 out of 200,000 *new born babies* (0.5 per 100,000) to 1 out of 2,800 (about 36 per 100,000), 72 times higher¹⁰⁵. A reliable estimate is included between 1 and 2 cases per 100,000. The incidence is variable in different countries and periods of time, and in the different typologies. Assuming an incidence of 1 out of 50,000, an annual frequency of 50 cases per week in the world can be estimated; 11 cases a year in Italy. These latest estimates

¹⁰³ In some cases this phenomenon is classified as the twin embolisation syndrome. The twin that dies and is squashed by the co-twin is defined as “papyraceous foetus”. The vanishing twin can die due to a defect of the embedding of the placenta, a defect in development that causes the dysfunction of a principle organ or due to the presence of a chromosomal abnormality incompatible with life. Often the vanishing twin manifests itself as a blind egg (membranes without an embryo, insofar as the embryo died in the first phases of development and was absorbed).

¹⁰⁴ H.J. Landy, S. Weiner, S.L. Corson, F.R. Batzer, *The “Vanishing Twin”: Ultrasonographic Assessment of Fetal Disappearance in the First Trimester*, in “Am. J. Obstet. Gynecol.”, 1986, 155 (1), pp. 14-19; H.J. Landy, B.M. Nies, *The Vanishing Twin*, in “Multiple Pregnancy: Epidemiology, Gestation and Perinatal Outcome”, L.G. Keith, E. Papiernik, D.K. Keith, B. Luke (eds.), The Parthenon Publishing Group, New York 1995; pp. 569-71; D. Pelega, A. Ferber, R. Orvieto, I. Bar-Hava, *Single Intrauterine Fetal Death (fetus papyraceus) Due to Uterine Trauma in a Twin Pregnancy*, in “European Journal of Obstetrics & Gynecology and Reproductive Biology”, 1988, 80 (2), pp. 175-176; J.L. Grosfeld, D.S. Stepita, W.E. Nance, C.G. Palmer, *Fetus-in-fetu: an Usual Cause for Abdominal Mass in Infancy*, in “Ann. Surg.”, 1974, 180 (1), pp. 80-84; C.E. Alpers, M. R. Harrison, *Fetus in Fetu Associated with an Undescended Testis*, in “Pediatr. Pathol.”, 1985, 4 (1-2), pp. 37-46.

¹⁰⁵ O.M. Mutchinick et al., *Conjoined Twins: A Worldwide Collaborative Epidemiological Study of the International Clearinghouse for Birth Defects Surveillance and Research*, cit., p. 276.

refer to *conceived* twins, including abortions too. The epidemiological studies are poor. The evident vagueness of the statistical data leads one to think that the epidemiological research is lacking and must be reinforced¹⁰⁶.

2. Prenatal diagnosis

The increasingly widespread use of prenatal diagnosis techniques (at least in the technologically advanced countries) increases the possibility of carrying out the early diagnosis of this pathology by means of ultrasound and, more accurately, also by magnetic resonance. In these cases the opinion of the consultant plays an extremely delicate role, to the extent to which he has to inform the couple of the present and foreseeably future conditions of the twins, the success of the operation after their birth and the long term consequences. Nevertheless, while it is possible to diagnose conjoined twinning, it is difficult to give a precise picture of the pathologies that might be associated with it. The diagnostic instruments - as refined as they may be - are often insufficient to express definitive opinions. For this reason the consultancy must be given by a multi-specialist team able to give information concerning the complexity of the condition diagnosed¹⁰⁷.

3. Ethical problems

Even though this is a relatively rare phenomenon, it deserves a proper bioethical investigation owing to the tragic nature and complexity of the correlated issues, which often call for evaluations and urgent decisions by the subjects involved, the parents and doctors in particular¹⁰⁸.

¹⁰⁶ There are four ethnic group categories in which there is a prevalence of the phenomenon: Anglo-Saxon/Caucasian, Chinese, Latin-American and Latin-European. According to statistics, it appears that conjoined twinning is statistically more frequent in the Latin-American ethnic group. A majority has been found in the female sex (thoracopagus twins) and in the male sex (parapagus twins and parasite twins). In the calculation of the incidence existing cases, diagnosed and aborted (by miscarriage or abortion) are not recorded.

¹⁰⁷ In this document, the NCB does not set out to go into the specific bioethical issue in the connection between malformations discovered during prenatal diagnoses and possible consequent choices to abort, but considers it right to stress how complex, controversial and - in the opinion of many - painful this question is. Reference is made to a previous document on this issue, *Prenatal diagnoses*, 1992, and, in this opinion, in point III.1, the concluding bioethical guidelines.

¹⁰⁸ On the one hand the lack of scientific and epidemiological studies is surprising, and on the other, the considerable amount of ethical studies is.

At the centre of the bioethical debate is the question of the *possible separation*. The progress in scientific knowledge and biomedical technologies (paediatric, reconstructive and transplant surgery) has made separation surgery possible which, until some decades ago, was impracticable, thus increasing the survival percentage and the quality of life of the twins¹⁰⁹. Such new possibilities for surgery raise various ethical issues with regard to the subjects legitimated to decide, the relationship between the possible risks and benefits for the life and quality of life and to the time at which to intervene.

It must first of all be underlined that the case of conjoined twins with only one head, extra limbs or parts of organs is not taken into consideration (the operation should not present ethical problems even if carried out only for aesthetic reasons, since in fact one single head identifies one single person), but reference is essentially made (with the exception of the case of the parasitic twin) to two persons, who can be characterised by having two heads and only one body, to having two heads and two bodies more or less complete and a variable number of limbs. The cases do not present problems where the conjoining is minimum (strips of skin or tissues) and the separation does not entail particular risks. The most complex cases are those in which the conjunction concerns extended parts of the body and the sharing of apparatus and vital organs, whereby the surgery for their separation seems indispensable to save the life of both twins or of one of the two probably to the detriment of the other or appears necessary to improve the quality of life, but implies a high risk with negative consequences that are difficult to avoid in relation to the delicate nature of the situation.

The ethical specificity of the problem concerns the peculiarity and uniqueness of the condition: conjoined twins are two distinct human subjects, insofar as each one is self-organised, but at the same time with organs and parts in common, whose communality can be necessary for their reciprocal survival. Their existence experiences not only a condition of physical connection, but often also of integration and reciprocal dependence (one cannot live without the other), even in the distinction of the individuality/personality. The phenomenon of conjoined twins constitutes a borderline case of the one-

¹⁰⁹ L. Spitz, E. Kiely, *Success Rate for Surgery of Conjoined Twins*, in "Lancet", 2000, 356, p. 1765.

self/other relationship, in a sort of ‘unitary duality’: they are seen as distinct but at the same time appear a unitary entity that forces them to have an integral interdependence. Another peculiarity is constituted by the fact that in many cases it is not possible to ascertain which twin depends on the other (apart from the case of parasitic twins).

In bioethical reflection the debate is above all on whether the integral physical independence (or the possession of a separate body) is an indispensable requirement to be considered a subject/individual that must be always guaranteed its ‘own’ specific integrity or whether we find ourselves before a different integrity, that is unitary and double at the same time, which must be recognised and respected when there are no imminent threats to its life, in its ‘own’ particular nature. What is the best interest to pursue for conjoined twins? What is the importance of medical diagnosis, the parents’ choice, the possible assent expressed by minors and how to configure the adults’ assent? What are and must be the limits of medical intervention on the body in the respect of the person?

The NBC highlights that the dramatic nature and complexity of the condition opens up dilemmas in which it seems that any ethical response or practical solution to the cases presented in reality is problematic. Proof of this are those situations that - made known to the public opinion by the media - have raised and raise contrasting emotional reactions by society, the difficulty of evaluation by bioethicists and complex decisions by parents and doctors.

In this Opinion the Committee discusses two situations often referred to in scientific and bioethical literature, deeming it appropriate to distinguish the position of newborn babies/minors from that of mature minors/adults.

3.1. Newborn babies/minors

3.1.1. A first situation is that in which there is no immediate danger to the life of the twins in the present and foreseeably immediate future, while separation by surgery, even though technically possible, is highly risky for the life of one or both twins¹¹⁰.

¹¹⁰ The word ‘risk’ is used in the general sense, even in the awareness that the evaluation of the likelihood of risk needs a precedent, which in many of the cases relative to conjoined twins is lacking.

Differing bioethical standpoints were expressed within the Committee which are reported below with their reasoning:

a. A first line of thought¹¹¹ considers that this choice to try and separate the twins is not ethically justified. In such circumstances in which surgery is not necessary, as there is no serious threat to the life of the twins nor a foreseeable worsening of the prognosis in the immediate future, the separation surgery is considered disproportionate owing to the high risks, as it could seriously compromise the life and health of the newborn babies or of one of them to the detriment of the other.

This standpoint appeals to the value of the twins' life, maintaining that the conjunction must not be considered in itself as an unacceptable condition. The physical, psychic and social limits that conjoined twins can suffer are ascribable to that general broad condition of disability set out by the UN Convention on the rights of persons with disabilities¹¹². And two persons with serious disabilities have an equal right to life and treatment regardless of the condition of their bodies, separate or not.

It was stressed that the seriousness of life must never be confused with the seriousness of treatment. It is not ethically or juridically licit to begin disproportionate treatment to avoid a life with disability. In other words, the modalities of treatment of conjoined twins cannot be evaluated with bioethical criteria that are different from those that must be used to evaluate the forms of treatment used for individuals with disabilities, considering that they are minors and cannot express their will. As far as the doctor is concerned, the deontological principle must not be neglected according to which before a situation of disability like that of conjoined twins, as before any other illness, they must always have the primary objective of doing their ut-

¹¹¹ Standpoint shared by the members: Profs. Stefano Canestrari, Bruno Dallapiccola, Antonio Da Re, Lorenzo d'Avack, Maria Luisa Di Pietro, Riccardo Di Segni, Marianna Gensabella, Assuntina Morresi, Andrea Nicolussi, Laura Palazzani, Vittorio Possenti.

¹¹² UN, *Convention on the rights of persons with disabilities*, 2006, to which Italy adhered and which has been adopted in its legal system, as expressed also by the NBC in a motion unanimously approved on 27 June 2008, in which it called for "the rapid approval of the law of ratification and implementation of the Convention". In art. 1, par. 2: "Persons with disabilities include those who have long-term physical, mental, intellectual or sensory impairments which in interaction with various barriers may hinder their full and effective participation in society on an equal basis with others".

most to safeguard life and health (present and foreseeable in the future), with the only limit of never having to resort to persistent therapy.

In these cases it must also be considered that waiting, if the situation is not life-threatening, finds a further justification in allowing the parents ‘to gain time’ so that they, with the help of the doctors, might better evaluate the clinical condition of their children and arrive at the best solutions for their health. For these reasons high-risk separation surgery is not considered ethically justified as it would result in configuring a form of ‘experimental persistence’.

In the light of the legal system in force it must also be borne in mind that if there is no serious and imminent danger it is not justified to intervene, placing the life of the minor at high risk. Should the parents or doctors express their dissent, it is up to the judge supervising guardianship to decide on the best objective interest of the minors.

b. A second line of thought, departing from the same philosophical assumption of the recognition of the value of life and health, considers that such value can be thought of only in terms of identification and considers conjunction an unacceptable compromising of human identity. It considers that individuality is also an essential element of such values and must be guaranteed when a reasonable possibility of success of the separation surgery exists even at high risk, as long as it gives hopes of success although scant.

The motivations can be two, different from each other, even though in fact partly overlapping and operationally converging.

A first motivation is that of those¹¹³ who, denying that the conjunction might be defined as a form of disability and even as a form of ‘acceptable’ disability, consider that however high the risk of the separation may be it is still proportionate to the pathology to be dealt with. To the extent to which the separation is not technically possible and in the absence of any threat to life, the right of the conjoined twins to live must be recognised.

According to others¹¹⁴, separation surgery would be justified insofar as aimed at guaranteeing the twins or one of them a certain quality of life. Con-

¹¹³ Standpoint shared by the members: Profs. Luisella Battaglia, Francesco D’Agostino.

¹¹⁴ Standpoint shared by the members: Profs. Salvatore Amato, Silvio Garattini.

joined life is considered contrary to a fulfilled realisation of the person, in so much that it annuls autonomous individuality and constitutes a form of ‘abnormality’ or ‘serious anomaly’ going beyond the very context of disability. It would be a serious responsibility to condemn someone a priori to a difficult existence from every personal and relational point of view, when the possibility exists - even though slender - of guaranteeing ‘normality’.

c. A third line of thought¹¹⁵ instead considers that it is not possible to abstractly judge the licitness/illicitness of high-risk surgery, even in the presence of a life-threatening situation.

Not only can there be forms of conjunction that give rise to particularly serious disabilities, but as is highlighted below, very often these forms of twinning are accompanied by malformations of the vital organs which will worsen in time. In these cases it can be ethically acceptable for the parents and doctors involved, on the basis of a reasoned evaluation of the situation of the specific case, to operate immediately even if the surgery is extremely risky.

3.1.2. A second condition is the one in which, on the basis of an objective clinical evaluation supported by empirical data, the clinical certainty is shown of the imminent and serious threat to the life and health of both twins. The abstention from surgery by the doctor will entail the death of both twins or a foreseeable worsening of the prognosis, while the separation of the two twins can present two outcomes: the first to save both lives; the second to save at least one of the two.

It must be recalled that very often these forms of conjoined twinning are accompanied by very serious multiple malformations, affecting organs and/or entire apparatus, like for example the heart and circulation system, whose functioning is compromised in such a way as to make it impossible for both twins to continue to live united.

Surgery to save both lives can be actually presented only in the condition of conjunction in which the missing organs could be transplanted and the body parts reconstructed. This is a very difficult situation to realise from

¹¹⁵ Standpoint shared by the members: Profs. Laura Guidoni, Monica Toraldo di Francia, Grazia Zuffa.

a medical and practical point of view. On the contrary the possibility is more frequent of an operation in which it is known beforehand that it is not possible to save both twins, but that there is a fair chance of saving only one of the two, the ‘strongest’ or ‘healthiest’, or the one that has greater anatomo-physiological chances¹¹⁶. The arguable expression ‘sacrificial separation’ is often used. It is not therefore a separation owing to the need to eliminate the impediment to the physical independence of the two babies, but of surgery determined by a serious condition of their health, such as to jeopardise their lives.

In these cases the particular difficulties in which the decision-making process comes about must not be neglected or made light of. Before the immediacy and urgency of surgery a difficult psychological condition of all the subjects involved in the decision is presented, whether they be the parents or doctors. It must be added that any decision taken by the parents should be founded on their real understanding of adequate and correct information, which is at times difficult, since not always do the doctors have a clear idea of the prognosis in the circumstances characterising the twins’ health. Nonetheless this cannot and must not exempt the doctors from giving the parents all the information necessary so that they can take part in the decision-making process in full awareness. It is clear that adequate information on the risks of possible surgery, pain treatment and the uncertainty of the prognosis must be intensified beforehand.

The Committee deems it appropriate to call the attention to some of the varying opinions and reasoning more frequently expressed on this condition in bioethical literature: those that for the most part were examined during the hearings and debate held during the discussion on the opinion, even if not necessarily shared completely or in part.

a. A first line of thought considers¹¹⁷ that the parents’ choice would be ethically understandable and acceptable who, following adequate medical information and also in contrast with this, in the uncertainty of the outcome

¹¹⁶ The hypothesis whereby only one can be saved and both have the same probability of survival is considered as a ‘textbook case’, not realised in practice.

¹¹⁷ Standpoint shared by the members: Prof. Carlo Flamigni.

of possible separation surgery, decide to abstain from the operation, even though knowing that such choice will entail the death of both twins or of one of the two. This position can be motivated by many arguments: by reasons of a religious nature, the intention to make a choice not made at the moment of the prenatal diagnosis (or that is the choice to terminate the pregnancy), by the refusal to assume the responsibility and the moral burden of a choice should the surgery permit the survival or the possible survival of one twin only, by letting ‘nature run its course’, by the parents’ will to avoid making the twins suffer owing to the operation and possible successive operations, bearing also in mind the fact that often a poor quality of life for both can be hypothesised with considerable healthcare costs.

b. Another line of thought¹¹⁸ is in favour of surgery aimed at saving both twins, but is ethically against any surgery that a priori will not allow the saving of both twins¹¹⁹. It is in fact believed that the protection of the gift of life must be understood as an absolute prohibition to cause death and, therefore, the inevitable dramatic choice of one of the two twins is considered illegitimate. The surgical separation would moreover question the principle of equality according to which all subjects must be recognised the right to life regardless of their condition of health/illness.

c. A further line of thought considers that in the condition of an imminent and serious threat to the lives of both twins and in the face of an appreciable and reasonable forecast of a life-saving outcome for one of the twins - on the basis of rigorous clinical tests - the surgical separation must be considered ethically correct and the doctors’ intervention justified.

The members of the Committee who shared this standpoint¹²⁰ were nonetheless keen to stress the fact that they do not share some of the ar-

¹¹⁸ Standpoint shared by the members: Prof. Maria Luisa Di Pietro.

¹¹⁹ This is what happened in the case of the Maltese parents with their conjoined twins Jodie and Mary, a widely debated case in bioethical literature.

¹²⁰ Standpoint shared by the members: Profs. Salvatore Amato, Luisella Battaglia, Stefano Canestrari, Bruno Dallapiccola, Antonio Da Re, Francesco D’Agostino, Lorenzo d’Avack, Riccardo Di Segni, Silvio Garattini, Marianna Gensabella, Laura Guidoni, Assuntina Morresi, Andrea Nicolussi, Laura Palazzani, Monica Toraldo di Francia, Giancarlo Umani Ronchi, Grazia Zuffa.

guments in literature supporting this thesis. To summarise: a) surgical separation is justifiable insofar as the ‘weak’ twin can be considered as a ‘donor of organs’, in the viewpoint of a ‘self-sacrifice’ for the wellbeing of the other with greater chances for the future; b) the death of the ‘weak’ twin is justifiable insofar as, according to a current terminology in literature, the ‘unjust aggressor’¹²¹, who threatens the life of the strong twin who, before such threat, can legitimately defend itself (in other words, a reaction against the aggressor would be justified even if it causes his/her killing in so much as being the only means to save his/her own life); c) the ‘weak’ twin is ‘destined to die’, would therefore die anyway, and thus it is allowed to make him/her die in advance; d) surgery is justifiable with reference to the theory of the ‘double effect’: the realisation of an unnecessary planned operation to obtain the survival of only one baby (intentional positive effect) produces the death of the ‘less healthy’ child as an unwanted negative effect.

The criticisms of these arguments can be summarised as follows: a) in this context the donation of organs cannot be invoked insofar as it presupposes the informed consent and the absence of risk for the life of the donor: the common shared organs - if equally connected to the physiological systems of the twins - are part of the corporeity of both and cannot be arbitrarily taken away from one to the advantage of the other; b) the ‘weak’ twin has no capacity to act and therefore to attack; the lack of will and intentionality determines the failure of any form of charge and can instead represent an involuntary ‘biological threat’ for the life of the other; for some therefore it cannot be considered an ‘unjust aggressor’, for others it is nevertheless an aggressor, even though an unintentional one; c) the ‘destination to death’, as foreseeably certain as it may be, does not amount to death; such future event is not sufficient to justify the decision to make a subject die in advance to save the other; d) the ‘double effect’ theory - often used also in the context of medical ethics - foresees different versions, formulations and expressions referring to different and even contrasting theories and assumptions, often giving rise to equivocal ones.

¹²¹ Terminology taken from the debate on the unjust war and legitimate defence since Scholasticism, but already present in the Talmudic debate that speaks of the right of the rodèf, “the pursuer”.

In such a context, the surgical separation is instead justified for these members of the Committee on the ethical and juridical principle of the protection of life. Therefore, the emphasis is placed primarily on the hope of saving both twins, but if this is not possible, at least of guaranteeing one of the twins a prospect of life that would be inevitably precluded by the choice to let nature take its course.

The aim of the operation is not to bring about death but to save a life and it is justified in the perspective in which there are no other alternatives and it is not possible to operate for the benefit of one without negative consequences for the other, who must nevertheless receive all the medical attention necessary to guarantee a painless end.

It is not therefore a question of choosing the ‘strongest’ of the two twins ‘at the drawing board’, or of evaluating that the life of one person has more or less value (against the principle of equality), but of ascertaining the medical response by the parents, on the basis of rigorous clinical tests, in line with internationally recognised scientific standards, according to which it can be excluded that one of the two twins has any, even though slender, chance of living and that the continuation of his/her existence determines the death of the other twin that could otherwise be saved. The option to ‘let nature take its course’ in the medical certainty of the death of both, would represent negligent conduct and the abandoning of therapy as it would prevent the saving of the saveable life.

In all these cases the surgery must be ‘reasonable’, or that is, it must exclude those levels of extreme experimentation whereby the suffering of the persons subject to it - newborn babies in this case - is not balanced by adequate life expectations.

3.2. Mature minors and adults

The decision to surgically intervene or not, both in conditions of necessity and non medical necessity, takes on a different moral relevance if the conjoined twins (extremely rare cases) are adult and both competent, or if they are mature minors. In this case, the informed autonomous consent/dissent of the subject’s decision in the request must be recognised, with prior exhaustive and calibrated mandatory consultancy with respect to the conditions of the subjects by the doctor or, even better, a medical team.

Such expression of autonomy raises a number of moral problems in consideration of the peculiar condition of the conjunction of corporeity.

In the situation in which both wills are in agreement with respect to operate or not operate in the consideration of the possible future scenarios outlined by the doctor, also to the extent to which the surgery or non-surgery can inevitably bring about the death or threaten the life of one of the twins, such decision is generally considered acceptable (if the operation is proportionate).

Cases of conflict are not known of, insofar as conjoined twins have until now expressed agreement both in their acceptance and refusal of treatment. Their life of being always conjoined brings about not only a physical but also psychic and emotional union (even though having different personalities), to the point that adult twins - to the extent to which they are competent - positively assess their life and their peculiar conditions; they refuse to be separated even if it is the only condition to continue to live; they refuse to be separated in the case in which they know that their survival would entail the death of the other twin¹²².

Insofar as - abstractly - a possible contrast of will takes shape with respect to the choice of separation, given the risks of the operation for the subject that chooses, but at the same time for the subject that undergoes this choice even though not sharing it, it must be considered that it is not only the individual right to self-determination that is being questioned, with all the problems related to the decisions that can jeopardise life, but also the duty that the twins have to respect each other's integrity. For this reason, therefore, the choice of the twin refusing treatment must be privileged so as not to jeopardise his/her own life.

Another extreme possibility is represented by the choice of one of the twins to sacrifice him/herself for the other. The details of the case record will not be dealt with in this Opinion but only a general ethical criterion will be formulated: the assent of the patient never represents an obligation for the surgeon to operate, while the dissent represents an obligation to not op-

¹²² In the rare cases known until now, many conjoined twins refused to be separated upon reaching maturity. For example, in 1967 Mary and Margaret Gibb refused separation, even when the imminent death of one of them owing to a tumor would have meant the unavoidable death of the other.

erate. There is then the absolute right of the mature minor to be informed for a consent or conscious dissent, since also before complex existential choices adolescents manage to prefigure the future and to assume the responsibility in conformity with their own life project¹²³. Choices that confirm the inappropriateness to establish rigid criteria that set out the acquisition of the full capacity to act and how, on the other hand, a case by case evaluation is suitable of the capacity of each single minor finding him/herself in that specific situation.

Bioethical guidelines

The reflection of the NBC has highlighted the problematic nature of the evaluation of the question of the treatment of newborn/minor conjoined twins, both by parents and doctors, in relation to the choice to intervene or not to separate them in the various clinical cases outlined above. All the more so that such standpoints, expressed theoretically (in order to give guidelines and direction in particularly difficult cases at clinical and ethical level), must always and nonetheless be pondered on the basis of relevant objective data and rational reasoning, in the context of the complexity and variability of the actual cases.

Despite the above mentioned differences, the Committee arrived at the formulation of a number of shared recommendations that may constitute a conceptual reference horizon to foster ethically complex decisions at clinical level:

a) research on the causes of the phenomenon of conjoined twinning must be promoted and increased, at scientific and epidemiological levels in order to understand its etiology and pathogenesis. Conjoined twins cannot only be considered a problem to be avoided (through prenatal diagnosis), but also to understand, prevent and treat with an interdisciplinary approach. The professional training of doctors and healthcare staff must furthermore be increased so as to build a team able to deal with such complex cases, also in suitable healthcare facilities;

¹²³ Principle which appears in various regional and international documents, among which: *Convention on the rights of the child* (UN, 1989, art.12) and *Convention on Human Rights and Biomedicine* (Oviedo, 1997, arts. 6, paras. 2 and 24).

b) the information to the parents, within the prenatal diagnosis of conjoined twinning - also owing to the limits of the technologies that can be used in this phase to define the anatomy and physiology of the origins with precision - must be given by a multi-specialist team of doctors, made up of different consultants in relation to the typology of the conjunction, or that is to say, with a close examination of the possible implications in relation to the chance of living, the quality of postnatal life, the success of the separation by surgery. It must be recalled that the information is not always clear and definitive, given the complexity and the unforeseeability of the condition. The information must be continuative - for the duration of the entire and complex course of treatment - according to the evolving of the conditions and must bear in mind the ability to understand and psychological-emotive difficulty of the parents, envisaging also help and psychological support in therapeutic alliance;

c) there must be no surgical intervention in the cases in which clinical conditions of persistent or experimental therapy are presented. Even though recognising, owing to the exceptional nature and complexity of the cases, the difficulty in establishing a clear demarcation line between proportionate and disproportionate or experimental interventions/treatments, it is to be hoped that in the various cases the parents and doctors can come to unanimous choices in the search for a balance between the prospects of life, quality of life and therapeutic needs;

d) considerations related to the costs of the healthcare assistance must not come into the ethical evaluation of the duty to operate or the abstention from surgery;

e) conjoined twins have the right to rehabilitation, the continuity of treatment and integrated physical-psychic-social assistance;

f) the role of the ethics Committee is important in supporting the decisions to be taken by parents and doctors;

g) the possible clause of conscience raised by the doctor or the medical staff for the assistance that is in conflict with their clinical and moral convictions, must be commensurate with the particular nature of the intervention and the circumstances, especially in the case in which the professional, with his skills, represents a 'crucial' and irreplaceable element for therapeutic success;

h) the confidentiality of the case must be respected, even to prevent the mass media from interfering with the delicate decision-making process;

i) in the case of adults, the will of the twins must be considered identical to that of any other competent adult, even with reference to the choice to undergo experimental treatment or to refuse therapy.

Presidenza del Consiglio dei Ministri



HEALTH “WITHIN PRISON WALLS”

27 September 2013

Presentation

The Opinion, deals with the issue of the right to health care for male and female prisoners, continuing and integrating the previous Opinion “Suicides in prison. Bioethical indications” (25 June 2010), the theme takes on particular ethical significance, for several reasons: in the first place because the prison population represents the high vulnerability category, whose level of health, even before entering prison, is, on average lower than that of the general population. Moreover, the principle of equal opportunities (between detainees and free individuals) to access health, perceived as a good, on the one hand it encounters obstacles represented by the need for security, while on the other, it is in contradiction with the practice of imprisonment which leads to suffering and disease. Consequently, all competent authorities, starting with those concerned with health care, have a duty to supervise and verify the effective compliance with the right to health of prisoners.

In line with international bodies and with the dictates of the prison health care reform of 2008, the right to health, even and especially in prison, is not limited to the provision of adequate healthcare services: special attention should be paid to environmental components, ensuring to those imprisoned acceptable living conditions and prison regimes that allow them to lead a dignified and fully human life. Therefore, problems such as overcrowding, poor sanitary conditions, lack of activities and opportunities for work and study, confined for most of the day in the cell, the difficulty in maintaining emotional relationships and contact with the outside world, are to be considered critical obstacles in exercising the right to health.

The Opinion aims to highlight the shortcomings of the prison system in relation to the health of prisoners and identify some key areas for intervention. In its recommendations, the NBC, taking as a starting point the condemnation of Italy for prison overcrowding by the European Court in Strasbourg in January 2013, reaffirms the value of prevention, in order to ensure that male and female detainees live in an environment that respects the rights and principles of humanity. Finally, it calls for supervision to ensure that the prison sector, which requires much effort to accomplish acceptable standards of living, and conversely does not have to suffer from the reduction in resources.

The Opinion was drawn up by Prof. Grazia Zuffa, coordinator of the working group. Numerous expert consultations have served to bring light on

issues requiring attention by the NBC. Special thanks to those consulted by the Committee for their contributions: Dr. Laura Baccaro (Ristretti Orizzonti - Padova); Dr. Teresa Di Fiandra (Psychology Director for the Ministry of Health, Directorate-General for Prevention);

Dr. Ronco (Associazione Antigone); Dr. Antonio Cappelli (volunteer doctor in Rebibbia for the Associazione Antigone); Dr. Paola Montesanti (Director of the Department of Penitentiary Administration); Dr. Fabio Voller (Director of the Social Observatory of Epidemiology, Tuscany Regional Agency of Health); Dr. Alberto Barbieri (General Coordinator of the organisation Physicians for Human Rights); Dr. Adriana Tocco (Guarantor of persons subjected to restrictions of personal liberty); The lawyer Riccardo Arena (Director of prison radio); Hon. Rita Bernardini.

The following Professors participated in the working group: Canestrari, Caporale, Gensabella, Palazzani, Toraldo di Francia, Guidoni. In particular, Amato, Canestrari, d'Avack, Toraldo di Francia contributed to the drafting of parts of the text and discussion.

The text was unanimously approved by the following professors who were present: Amato, Battaglia, Canestrari, D'Agostino, d'Avack, Da Re, Dallapiccola, Flamigni, Forleo, Garattini, Guidoni, Isidori, Morresi, Neri, Palazzani, Piazza, Possenti, Scaraffia, Toraldo di Francia, Umani Ronchi, Zuffa. Prof. Marianna Gensabella subsequently also expressed her approval.

The President
Prof. Francesco Paolo Casavola

Premise

The National Bioethics Committee has already expressed its opinion regarding the serious problems of those who are obliged to live in confinement “within prison walls” starting with the declaration of January 2003 denouncing the dramatic conditions of overcrowding in Italian prisons, and in the most recent Opinion “Suicides in prison. Bioethical indications” 25th June 2010. In that document, it is noted that the phenomenon cannot be interpreted solely individually, as a sign of psychological distress or of the detainee’s psychiatric disorder/pathology; but also as a symptom of a lack or insufficiency of collective responsibility towards the fundamental rights of detainees, particularly the right to health. In its previous standpoints the NBC did not decline to allude to the challenging problem of the almost irreconcilable incompatibility of the prison system with the right to health, in its broadest sense, it is of specific bioethical importance: this incompatibility is exposed day by day - at least in Italy - it is absolutely evident, at least to those who do not want to close their eyes to this reality.

It should be recalled, however, very schematically, already in this preamble some elements-principles which form the theoretical and conceptual framework within which the NBC has addressed, in several documents on specific themes and specific conditions, the problems connected with the protection of human health¹²⁴. The first element is recognition that the problem of health comes necessarily within the broader framework of the discussion on fundamental human rights, as in Article 25 of the Universal Declaration of Human Rights, the actual enjoyment of these rights is a primary factor for the effective protection of health as a good¹²⁵. From this there is also underlined how the health status of an individual is determined by the ability to take advantage of a variety of resources, both direct and indirect (such as e.g. housing situation, environmental health, lifestyle, degree of education, working conditions, etc...), corresponding to the different levels of possible interventions on the factors susceptible to modification and cor-

¹²⁴ See, in particular NBC *Bioethical guidelines for equal access to healthcare*, 25 May 2001, *Bioethics and the rights of the elderly*, 20 January 2006; *The living conditions of women in the third and fourth age: bioethical aspects of social health care*, 16 July 2010.

¹²⁵ See NBC, *Bioethical guidelines for equal access to healthcare*, cit.

rection to mitigate existing inequalities. A second element concerns, more specifically, the theme of those inequalities in health that are considered unfair as predictable, preventable, correctable, and therefore ‘morally unjust’. In this respect, the NBC has repeatedly reaffirmed the principle according to which the effort of the institutions in charge of ensuring equal opportunity to achieve the maximum health potential possible for each individual - which will necessarily be different from one individual to another - should be aimed at favouring, the most disadvantaged groups and individuals, when distributing scarce resources, such as those typical of the health sector; in other words, it is the same concept of (distributive) equity, or if one wishes, of substantive equality (expressed in the 2nd par., Art. 3 of our Constitution), to require not only unequal treatment to compensate for situational disadvantages¹²⁶ but also careful monitoring so that forms of ‘covert rationing’ do not constitute actual barriers to access healthcare services for the weaker sections of the population.

Coming back to the prison situation, the disproportion between the dimensions of the gestures of self-harm and self-suppression of life within and outside “prison walls” has led the Committee to consider the harsh, often inhumane living conditions in Italian prisons as an environmental factor that adversely affects the physical and mental health of the prisoner and aggravates the discomfort inherent to the loss of freedom.

Hence the purpose of dealing with the various aspects of health in prison, in the belief that the right to health for prisoners represents the first right, which influences fulfilment of other rights; and conversely, that enjoyment of basic human rights conditions the state of health. To fully understand this statement, it is necessary to define the comprehensive meaning of the right to health: not only as a right of the detainee to be treated and as far as possible to not get sick, but also as a right to lead a dignified and fully human life, with the possibility of self fulfilment through some kind of existential projectuality. Claiming the right to health in the global acceptance is essential for anyone who is forced to live in prison where time is often devoid of purpose and meaning. For this reason, the achievement of this right

¹²⁶ See A. Pizzorusso, *Equality; Right*, in “Encyclopedia of Social Sciences”, Treccani, vol. III, 1993.

meets serious obstacles in the concrete reality of prison itself: even more so because those who are not free have difficulty, due to their very condition, in making their voices heard.

*A Prison is a place of contradictions*¹²⁷: the contradiction between the principle of equal rights inside and outside the prison walls (with the exception of freedom of movement), and the security requirements that tend to limit them; the contradiction regarding the norms according to which institutions must ensure the “healthiness of the living environment” and “the highest hygiene standards provided by law¹²⁸”, and the real living conditions in overcrowded cells; the contradiction between the significance of the sentence, based on individual responsibility, and the concentration in prison of an increasing number of people who belong to the most deprived strata of the population; the contradiction of the deficit in the health of those who enter penitentiary institutions and the prison which produces suffering and disease.

These are just some of the reasons which invoke ethical responsibility towards detainees in that they are from a biopsychosocial perspective a highly vulnerable group.

There are also other reasons to exercise constant public attention to the health of detainees. The effective exercise of the rights of those confined enters into contradiction, as we have said, with the very condition of the deprivation of liberty, a key aspect of which is constituted by “subtraction from view” of the bodies of the detainees and the environments in which they live. Although in recent decades there has been introduced as a democratic objective a prison which is (more) “transparent” and connected to the territory, modern prisons still retain to a large extent the historic character of “dungeons”.

¹²⁷ Comité National d’Ethique Consultatif pour les Sciences de la Vie et de la Santé, *La santé et la médecine en prison*, Avis 94, 26 October, 2006. In particular the Committee denounces (p. 8): “Prisons are also the cause of illness and death: they are the scene of regression, despair, self-inflicted violence, suicide”.

¹²⁸ *Guidelines for the NHS interventions to protect the health of detainees and internees in penitentiary institutions and minors subjected to criminal measures* of the Decree of the President of the Council of Ministers of April 1, 2008 (*Procedures and criteria for the transfer to the National Health Service of health functions, employment relations, financial resources, equipment and capital goods in the field of prison health*): “to guarantee the healthiness of the environment” is set as a priority.

This requires the constant duty of knowledge and monitoring of the observance of the rights of detainees, as well as reporting violations and non-compliance.

Regarding this, we note with dismay the deterioration of the living conditions in prisons, during the ten years which separate us from the first statement by the NBC in 2003 to the ruling of European Court of Human Rights on 8 January 2013¹²⁹, which judged life in overcrowded Italian prison cells as “inhuman and degrading treatment”.

1. Health in prisons and human rights: guiding principles

We do not intend here to enter into the debate on the role of the sentence. We start from the recognition that prisons in themselves can be pathogenic institutions, an inducer of psycho-physical disorders which determine in those imprisoned, in the form of legal suffering, a surplus of affliction and therefore of the sentence. The studies of Daniel Gonin, in the second half of the eighties of the last century, described in a scientific and articulate manner the suffering in prison and the illnesses that affecting the body of the prisoner during the course of segregation¹³⁰. Legal suffering, if nothing else, with a wide exploitation of the offender, it is always the main cause of the altering in structure and of debilitation of the prisoner and determines a spectrum of pathologies, of “shadow diseases”, considered as essential characteristics of “immaterial imprisonment”. The successful expression of Nils Christie icastically summarises the essence of an unclassifiable sorrow and suffering for its own sake, completely extraneous to the development of the value of punishment, understood as the evolution and transformation of the prisoner¹³¹. The highest standards required in the protection of human rights and fundamental freedoms in modern societies involve correspondingly and unavoidably, greater firmness when assessing violations of the essential values of democratic societies, even towards prisoners.

¹²⁹ Torreggiani and others vs. Italy (Sent. 8 January 2013).

¹³⁰ D. Gonin, *La santé incarcérée. Médecine et conditions de vie en détention*, L'Archipel, Paris 1991; ital. transl., *The body imprisoned*, EGA, Turin 1994.

¹³¹ N. Christie, *Limits to Pain*, trans. ital. *Abolire le pene? Il paradosso del sistema penale*, Edizioni Gruppo Abele, Turin 1985. Nils Christie is epigone of abolitionist thought of imprisonment.

It should be noted that Article 3 of the European Convention of Human Rights (ECHR) - in continuity with the provision in Article 27, III par., of the Constitution - provides the prisoner an absolute and binding protection, prohibiting the infliction of sentences which are of an inhuman and degrading nature. The most recent application of Article 3 ECHR can be considered as the normative cornerstone for the psycho-physical protection of the prisoner¹³².

The judges in Strasbourg, while noting a minimum threshold of suffering intrinsically inherent to any form of deprivation of liberty, have identified a wide range of situations of an objective nature (such as overcrowding, poor sanitary conditions, lack of ventilation) and of a subjective nature (referring to the incompatibility of detention with health conditions of the prisoner) which integrate a violation of Article 3 ECHR.

The assumption that is more frequent statistically is certainly represented by prison overcrowding, made the subject of recent critical condemnation in the judgment of the European Court of Human Rights (*Torreggiani and others vs. Italy*).

According to the now settled case law, the Court automatically includes as inhuman and degrading treatment when each prisoner has a personal space that is equal to or less than three square meters (compared to at least four sq. m. as recommended by the Committee for the Prevention of Torture of the Council Europe).

What matters, for the purposes of this document is the fact that the Court has clearly revealed the existence of the structural problems that are at the origin of the violations alleged in the serial appeals. In addition, while stressing that its task is not to indicate the specific measures to be taken in this context, the Court does not hesitate to provide some important indication in this regard, first of all, recalling the recommendations, Rec (99) 22 and Rec. (2006) 13 of the Committee of Ministers which invites States, and in particular prosecutors and judges, as widely as possible to resort to alternative measures to detention and to redirect their penal policy toward less use of detention for the purpose, inter alia, to reduce the growth of the prison population (§ 95).

¹³² Article 3 ECHR: no one shall be subjected to torture or to inhuman or degrading treatment or punishment.

Secondly the Court points out that the Italian government should adopt - at the latest, as pointed out several times within one year from the passing of the court decision - a system of adequate domestic appeals to ensure a *preventive* remedy against violations of Article 3 ECHR borne by prisoners (and therefore suitable to stop the violations taking place), as well as a *compensatory* remedy in cases where infringement has occurred (§ 96).

In conclusion, it is clear that there is the need for a complete re-examination of the “government surplus” in a pluralistic and multi-dimensional approach, to allow the consolidation of different perspectives. If the prison sentence is unavoidable, it should be considered an expressive entity which cannot impose the defense of liberty through its negation.

2. The prison population: health status

In penitentiaries there is a concentration of the persons belonging to the most marginalised groups in society, with low levels of education, with lower standards of health and with chronic diseases left untreated. This statement is contained in the “Moscow Declaration on health in prisons as part of public health”, adopted in 2003 by the Regional Office for Europe of the WHO¹³³. Among those subjects over-represented in prisons compared with the general population, there are also cited drug users, those most vulnerable and those involved in risk taking behaviour such as injecting drugs and sex for money. In fact, epidemiological studies on the prison population are limited, suggesting that prisons are still regarded as a separate world: the integration of health in prison in the channel of public health is to be considered an auspice rather than a reality. Just think of the national surveys on the health status of the general population which almost never include detainees: this applies for example to the *National Health Interview Survey* (United States) and ISTAT surveys on the Italian population.

This oversight (or discrimination) is all the more deplorable when one considers the high numbers of people locked up in prison, and the number

¹³³ WHO Regional Office for Europe, *Health in prisons*, 2007, p. 10.

is constantly rising: in 2012, there were more than 10.1 million prisoners recorded in the world, the figure rises to 10.75 million if we consider the so-called “detention centres” where people are locked up even though they are not subject to criminal proceedings. The United States holds the record of the highest incarceration rate in the world (743 per 100,000), followed by Rwanda (595), Russia (568)¹³⁴.

Despite the lack of systematic measurement, the WHO informs that the major disorders in prison are mental, communicable, and gastrointestinal disorders. Certain unhealthy behaviours, such as tobacco consumption and alcohol abuse, associated with malnutrition and lack of physical activity, can aggravate serious chronic diseases such as diabetes and hypertension, which have a higher prevalence compared to the non-institutionalised population. A large part of non-communicable diseases, such as diabetes and heart disease could be reduced by acting on the major risk factors. Hence the WHO guidelines: 1) increasing physical activity; 2) information and education on healthy lifestyles; 3) special courses for more vulnerable persons, the elderly and the overweight; 4) special courses of gymnastics for vulnerable groups¹³⁵.

As to communicable diseases, the prison population is exposed to the spread of infectious diseases related to the use of injected drugs and risky sexual practices. A particular warning is launched by the WHO for HCV (Hepatitis C). Lastly, prisoners are subjected to high levels of stress, anxiety, sleep deprivation, which affect physical and mental health.

In Italy, with the Decree which set the passage of the prison health system to the National Health Service (see below, par. 4), the acquisition and the organisation of epidemiological knowledge have been pointed out as priorities: Regions should activate in all penal institutions a systematic survey of data “on the prevalence and incidence of pathological states, also describing the conditions and risk factors that favor onset or hinder cure”¹³⁶.

¹³⁴ R. Wamsley, *Prison Population List* (9th Edition), International Centre for Prison Studies, 2012.

¹³⁵ Who Regional Office, *Final report of the network meeting on prison and health*, Copenhagen 11-12 October 2012, presentation by Emma Plugge, Oxford University.

¹³⁶ *Guidelines*, cit., Attachment A, p. 4.

In fact, only few Regions have initiated such a systematic survey; let alone in each penal institution¹³⁷.

A recent study of national data confirms the different distribution of health problems among prisoners in relation to the general population: 13% of the prison population is at risk compared to 7% of the general population. The disproportion is particularly evident for some disorders: drug addiction reaches 21.5% among prisoners compared with 2.1% of the general population; 15.3% of prisoners have dental problems (compared with 4.5 among g.p.); 13.5% have osteoarticular and post traumatic diseases (vs. 11, 9 g.p.); 2.08% suffer from HIV infection (compared with 0.2 of the g.p.)¹³⁸.

¹³⁷ Of these indicated there is Tuscany, which provides for periodic surveys through the Regional Agency of Health. The Tuscan ARS has conducted a survey on the health of prisoners in Tuscany in 2009, a second has been ongoing since 2012. Here is the most significant data of the 2009 survey, which offer a glimpse of general validity: The detainees are predominantly young (86.4% between 18 and 49 years old), almost half foreigners (47.6%, against a 9.1% presence of foreigners over the whole population of Tuscany). The level of education is low: 84.7% with middle school certificate (while only 50.5% had this level of education in Tuscany). There is a high rate of obesity (11.5% among prisoners against 9.2% on the territory) a high prevalence of tobacco use (70.6% versus 33.2% among the free). Among the non-transmittable diseases, disorders of the digestive system prevail (25.1%), of which more than half are made up of dental and oral cavity diseases (covering 13.7% of prisoners). Digestive diseases are more prevalent among the prison population compared to the non-institutionalised, as well as diabetes and obesity. Following on are the diseases of the bone and muscle (11%) and circulation system (10.8%). Among infectious diseases, the most common are hepatitis C virus (HCV), hepatitis B virus (HBV) and HIV infection. These figures are high in comparison with the spread of these infectious diseases among the free population: HCV prevalence was 9% compared to 3% of the general population; HIV prevalence is 1.4% against 0.1% of the resident population. In addition, infections are distributed differently between Italians and foreigners. For example, among Italians some infections are much higher: HCV reaches 14.9%, HIV-2%. Such differences so marked among Italians and foreigners, however, give rise to many questions. In fact, they seem to conflict with international literature that reports high prevalence of hepatitis C virus infections in Africa in particular (it should be noted that Africans make up a large proportion of foreigners in the prisons of Tuscany). It would appear that the different numbers observed between Italians and foreigners are affected by different levels of adherence to virology tests (which require consent by the individual): of these cultural differences or simply communication difficulties also have an influence. With regard to mental health, the prevalence of mental disorders among the prison population is 33.3% compared to 11,6% of the general population. Among the disorders: diagnosis of drug dependency (12.7%), followed by neurotic disorders adjustment reactions (11.6%). When comparing those in confinement and the free, there is a higher prevalence of alcohol-related disorders among the first (5.7% versus 2%) and neurotic and adaptation disorders (10.9% versus 0.8%), while non-psychotic depression disorders are more represented in the general population (6.5% among the free versus 1.9% among those in confinement) (Voller F. et al., *The state of health of the prison population inside the penitentiary facilities of the Tuscany Region*, "Epidemiology & Prevention", 35, 5-6 2011, pp. 210-218).

¹³⁸ M. Esposito, *The health of italian prison inmates today: a critical approach*, in "Journal of Correctional Health Care", 2010, 16 (3), pp. 230-238.

Overall, the prison environment is confirmed as at risk: for mental disorders especially for neurotic and adaptation disorders, which are ten times higher among prisoners, confirming the stress of prison life; also infectious diseases, whose potential for transmission is made worse by promiscuity; as well as for cardiovascular disease and diabetes, linked to a sedentary lifestyle and poor eating habits.

3. A comprehensive approach to health in prison: international guidelines

As already mentioned, equality regarding health between detainees and free individuals does not only mean equality in the provision of health services: a good network of health services is, if anything, an instrument which is necessary but not sufficient, *to achieve equality in the levels of health*. Therefore, one must offer detainees *equal opportunities to access health*, as a good, taking into account the differences (in this case, the deficit) from the start in the levels of health, as well as the particular circumstances of life during deprivation of freedom which in itself represent an obstacle to the achievement of health goals. It should be mentioned that the lack of freedom is a major weak point in the patrimony of health in its social and psychological components. The most invasive consequence of institutionalisation is the loss of the dimension of privacy of the individual and his capacity to control the environment of everyday life, which manifests itself in loss of identity and the perception of insecurity.

For this reason, the condition of imprisonment requires with even greater urgency *a comprehensive approach to health in prison*, starting with a careful investigation of health needs (and not just the needs of health services) of the prison population, involving the prisoners themselves and the voluntary organisations working in the prison. In this survey, the environmental variables of health are crucial, paying due attention to aspects of the prison regime and daily life inside prison.

Not surprisingly, the WHO emphasises the risk conditions common in prisons bullying, mobbing, forced inactivity. We therefore recommend pursuing the goal of a “safe” prison, both in terms of health hygiene as well as security understood as protection from violence and abuse. Respect of human rights, together with acceptable conditions of prison life are the foundations of the promotion of health since they embrace all aspects of the life of the prisoner.

The choice of the comprehensive approach to health allows for assessment under a different light and also to strengthen aspects, such as treatment and rehabilitation of the prisoner: these become essential elements of the right to health, which therefore is presented as the basic right which supports all others. Similarly, the relational needs of prisoners gain importance, so much so that the contacts with the outside world and the maintenance of family relationships are the subject of specific recommendations by European institutions¹³⁹. This context should include the ability for detainees and spouses/partners to enjoy intimacy, so as to safeguard the exercise of affectivity and sexuality¹⁴⁰. In this way the ethical principle of the centrality of the person is substantiated, even in conditions of deprivation of liberty.

On an international level, the following actions deemed to be fundamental for the protection of health of the prisoner are emphasised: 1) the treatment of detainees must always comply with the law; 2) the cells and the services must be clean and well equipped; 3) it is necessary to pay attention to the demands of the prisoners; 4) it is necessary to protect detainees from dangers; 5) the prison regime should be bearable; 6) the staff must behave in an ethical and supportive manner.

Also indicated are some basic health interventions in relation to the specificity of prison life, to which a response must, in any case, be given¹⁴¹.

- Information and counselling on the prevention of communicable diseases, including those transmitted sexually, HIV and hepatitis;
- Information and counseling on lifestyles at high risk, including the risk of drug overdose immediately after release;
- Support for healthy lifestyles, including physical activity and diet;

¹³⁹ See the September 22, 1997 n. 1340 Recommendation of the Committee of Ministers of the Council of Europe, Article 6 which affirms the need to “improve the conditions for visits by families, in particular by providing places where prisoners can meet their families alone”; January 11, 2006 and Recommendation No. 2 Rule No. 24, paragraph 4 states that “the arrangements for visits shall allow prisoners to maintain and develop family relationships as normal as possible”.

¹⁴⁰ There are many European countries where the visits of partners are held in private spaces. In Italy, this is prevented by Article 18 of penitentiary regulations which imposes surveillance on sight of meetings between prisoners and family members by the Penitentiary Police. This norm has raised the objection of unconstitutionality by the Probate Court of Florence (Order n.1476/2012). Bills on affectivity in prison have been lingering in Parliament for many legislatures.

¹⁴¹ WHO, 2007 (cited above), pp. 16-17.

- Measures to promote mental health, including an appropriate space of time for social life; an occupation that is meaningful for the detainee (work, artistic activities, exercise); contacts with the outside world and aid so as to keep relationships with the family. If it is true that prison itself is a risk factor for health, it is also true that it can provide opportunities for health to persons who are particularly marginalised, who even when free did not have access (or full access) to public healthcare: in particular, migrants and the most disadvantaged and stigmatised population groups.

4. From the prison healthcare system to the National Health Service: the decree of transfer of health functions and planning objectives

To ensure adequate levels of health services to prisoners, it is necessary for healthcare in prison to become fully part of public healthcare, coming under the same authorities which preside over the services on the country's territory. This indication was reiterated in 1998 by the Committee of Ministers of the Council of Europe. Some European countries had previously conformed, such as Norway in the eighties or France in 1994. Others have done so later, such as the UK in 2002. In Italy, the passage of prison healthcare to the National Health Service took place in 2008¹⁴². In the attachment containing guidelines, particularly significant and advanced are the so-called "reference principles", including "recognition of the full equality of treatment for free individuals and detained individuals and internees and juvenile subjected to criminal measures"; "the need for full and fair inter institutional cooperation" between the NHS and Penitentiary Administration and the juvenile justice system.

Moreover, in full adherence to the comprehensive concept of health already mentioned, there is "*the complementarity between interventions in protection of health and interventions aimed at the social recovery of the offender, through actions and programs conducted with the participation of all the institutions concerned, social cooperatives, voluntary associations.*" In addition, the prominent role of detainees in the construction of health¹⁴³ is

¹⁴² Decree of the President of the Council of Ministers of 1st April 2008 (cited above).

¹⁴³ "The effectiveness of such integrated interventions is favoured by the direct participation of prisoners to prevention, treatment, rehabilitation, and preparation for exit".

recommended. Once again, explicit reference is made to “*ensure environmental and living conditions of detainees that meet the criteria of respect for the dignity of the person: avoiding overcrowding, respect for religious and cultural values etc*”.

The section on “Health Objectives and basic levels of care” is not limited to the field of provision of care services and adaptation of this offer within “prison walls”, but aims at prevention both in terms of individual responsibility (health education programs to promote healthy habits), as well as collective responsibility (“promotion of a healthy environment and healthy living conditions, while taking into account the needs of imprisonment and restricting freedom”).

The programmatic priorities are: 1) general medical practices; 2) specialist services; 3) responses to emergencies; 4) infectious diseases; 5) pathological addictions; 6) mental health; 7) protection of women prisoners; 8) protection of immigrants.

In addition, the Prime Minister’s Decree (Appendix C) indicates the guidelines for interventions in Judicial Psychiatric Hospitals and nursing homes and custodial facilities, with a view to their being superseded: in particular, in compliance with the principle of territoriality, the established user base of the regional service areas of individual institutions, in order to facilitate the taking in charge of the internees with a view to their discharge after completing the detention measure; and it is foreseen that there will be sections activated for treatment and rehabilitation inside penal institutions for individuals with a psychiatric diagnosis.

To facilitate and coordinate the action of the institutional levels involved in the implementation of the reform - in particular, the collaboration between healthcare institutions and penitentiaries - the cited Decree of the President of the Council of Ministers has set up two national Coordination Boards within the State-Regions Conference: the first for healthcare in prison, the second to supersede the JPH.

At the regional level, coordination is entrusted to the regional permanent observers for prison healthcare, for constant monitoring of the quality of the care in prisons.

After five years from the Prime Minister’s Decree of 2008, there are still several problems, both institutionally - the perfection of the functioning of the new system -as well as - and more importantly - as concerns the

fruition of services by detainees and, even more so, in terms of a real equalisation of levels of health inside and outside prison walls.

The main open issues

Among the various problems and shortcomings reported during the course of the consultations of experts, we particularly bear in mind:

- *The consequences of differences in the levels of healthcare services from one Region to another.* Following the process of regionalisation of public healthcare (amendment to Title V of the Constitution), the competencies have not passed from the Ministry of Justice to the Ministry of Health, but from the former to the Regions and Local Health Authority of areas in which the penitentiaries are located. This process of decentralisation has very different consequences on detainees compared to free individuals: indeed the former often find that they have been transferred from one institution to another, situated in different regions, and therefore may receive different services. As it is known, the broad measure chosen to ensure some kind of national homogeneity to the regional system is the establishment of Essential Levels of Care. This measure is undoubtedly useful for the general population and has an important social purpose. However, this basic homogeneity is not enough, for those who, like detainees are transferred from one region to another not of their own will and therefore can be denied treatment which they had received until the previous day in a different prison. In other words, there is a breach of the right to continuity of care. Continuity of care is also undermined by the absence of computerised medical records, to the detriment of *promptness* in the transmission of health information, as will be described below.

- *The lack of homogeneity from one Region to another in the implementation of the Permanent Observatory for prison healthcare.* The failure or inadequate functioning of the Observatory, not only retards the acquisition of epidemiological knowledge necessary for health planning, which is essential for effective implementation of the reform itself; but it undermines the confrontation/dialogue/dialectic between institutions responsible for health and institutions responsible for custody, given that the Observatory represents the highest instrument of inter institutional coordination. In the light of this failing, the custodial logic is likely to prevail over the right to health, in the name of preponderant security needs.

- *The difficulty in finding a framework for the implementation of the reform on a national level, always following the process of regionalisation.* To overcome this, the Board of ongoing consultation on prison health at the State-Regions Conference conducted in 2011 a series of consultations with representatives of regional permanent observatories. However the problem still remains.

Beyond equality of treatment

Certain problems stem from a mistaken conception of equality regarding the right to health, which is sometimes understood as “equal” treatment, without considering the different health needs of the prison population.

An example is booking for *external specialist examinations or hospital admissions for operations to be scheduled: the inclusion of prisoners in normal waiting lists* penalises them, because the possibility of attending the examination appointment once it is their turn depends on the availability of the police escort, which is not always assured. In these cases, the detainee misses the appointment and it can take a long time before another opportunity arises. More serious still is the case in which the prison administration must consult individual hospitals in search of availability for hospital admissions: while waiting for the response, further attempts to different structures are not carried out and in the not uncommon event that hospitals do not respond the hospital treatment does not occur or is postponed far off in time¹⁴⁴. The difficulties in obtaining external examinations for prisoners are confirmed by the data: the average wait is 40 days in Italy with a maximum of 90 and a minimum of 10 days¹⁴⁵.

Another critical area is *dental assistance* and the supply of dental prostheses. It is true that the NHS offers this service in a very limited manner to all Italian citizens and of course this is not about claiming superior services for prisoners. However, to be kept in mind are the special health needs of the group represented by detainees upon which this general lack of public health services has far more serious implications in relation to the particular severity of their oral conditions (see above paragraph 2). Therefore dental

¹⁴⁴ The case in example is the Poggioreale prison.

¹⁴⁵ M. Esposito, 2010, cit. p. 236.

care in prison should be a priority for health planning: for example reconstruction of proper masticatory function has important positive effects on the conditions of the digestive system and helps to restore a dignified look to the individual. Nevertheless, the reform did not increase this form of assistance evenly in all the Regions; indeed in some cases, assistance has even been reduced, without the intervention of some voluntary associations¹⁴⁶.

Inadequate responses to the specific health needs of the prison population are also recorded in the field of physiotherapy rehabilitation and *psychological assistance*¹⁴⁷. Typically, psychological assistance is provided upon entry into prison, but there is a lack of continuity later on. As regards the taking into care of mental disorders there is a lack of measures in the prevention of mental illness, particularly in the formation of self-help groups.

Lastly, *respect for privacy* is a critical point, as shown by studies conducted among prisoners¹⁴⁸.

5. The right to healthcare related to security requirements

As already stated, there is a contradiction between the assertion of the right to health of male and female detainees and the security requirements that tend to limit its being exercised (see the preamble). Security requirements exist, moreover, also in the aforementioned *Guidelines for action to protect the health of prisoners* reference is made to the services to be provided “respecting the security measures”. For this very reason it is important that the contradiction is always evident, especially to the institutions that deal with health. But also the institutions that preside over security must be fully aware of it, in order to exercise their duties having clear the limit represented by respect of the fundamental rights of detained persons. The translation of the right to health in concrete terms into “health as a good” depends on the government being aware of this contradiction, from its ensuring that this right is not in fact nullified in the name of a preponderant logic of security.

¹⁴⁶ The case in example is Rebibbia.

¹⁴⁷ The general shortage of psychologists is also reported in the expert consultations of the Permanent Regional Observatories of 2011 cited above.

¹⁴⁸ C. Sarzotti, *I medici penitenziari tra istanze securitarie e paradigma del rischio: un'indagine sul campo*, in Esposito M. (ed.), *Malati in carcere*, Franco Angeli, Milan, 2007. Half of health staff interviewed mentions the complaint of detainees for failure to respect your privacy.

Even in this regard, the health care reform is a major breakthrough because it opens the doors of prison to an institution, the institute of health, *whose first and only mandate is to promote the health of individuals and their protection as patients.*

Therefore, the Local Health Authority should have the responsibility not only to provide necessary interventions, but also to “represent” the interests of the person, especially if the person is sick, before the judicial and penitentiary institutions. Only by making explicit the different needs and with full awareness of having to find solutions to an underlying contradiction, can we move forward on the path of affirmation of the right to health, by finding a satisfactory agreement between the different needs and different institutional levels. We must always remember that in prison the logic of custody is in itself preponderant: therefore achieving the objective of health can only be the result of conscious efforts, as is recognised by the Penitentiary Administration itself¹⁴⁹.

Knowledge of the barriers to health in prison and their communication to the general public are thus of particular importance and are a requirement for the “transparency” of prisons, as already mentioned: this is necessary to make the rights of detainees concretely receivable.

In many cases, some of the impediments have more to do with the logic and routine of the prison institution than with security itself.

We will point out some critical areas, usually motivated by security precautions:

- *Shortcomings and delays in care for prisoners subjected to medium and high security measures*¹⁵⁰. Even when pathological states have been documented requiring continuity of care and assiduousness, in general, the Magistracy does not allow these prisoners external hospitalisation, but rather provides for admission to existing healthcare wards inside the prison. How-

¹⁴⁹ Ministry of Justice, *Planning Document of the Third Bureau, Health Service of the Department of Penitentiary Administration*, 2005: “The main challenge for the transformation of the pattern of health care in prisons is still the wide gap between the safety profile and the social/treatment profile including health. To bridge the gap between health and safety, intervention of a cultural nature should be taken into consideration even before regulations, which cannot stop at the gates of the prison...”.

¹⁵⁰ This complaint is also present in the expert consultations of the representatives of the permanent regional observatories by the Board of permanent consultation on prison health of the Joint Conference of Regions: the NBC was able to consult the report.

ever, the lack in number of these wards and their uneven dislocation on national territory mean that they do not provide adequate care.

- *Non-recognition of the state of incompatibility with imprisonment of persons with serious illnesses and disabilities.* In many expert auditions, there have been reported dramatic cases of sick or disabled persons, who live in conditions at the limit of human tolerability. In these cases, time in prison is a denial of the right to dignity¹⁵¹.

- *Denial of the right to die in dignity, as documented in the cases in the news*¹⁵².

- *Delays in emergency cases* at times with fatal results have been reported by other news stories. It should be considered that during the night for those in cells there is only calling by voice of the guard, which, in itself leads to delays in alerting the emergency unit.

Other shortcomings appear without a solid reason, except for mere prison routine that has been mentioned. It is worth mentioning:

- *The denial of the right to the choice of doctor.* This faculty, commonly exercised by the free citizen, often does not exist for prisoners because they are forced to see the general practitioner of the prison ward; or else an examination by the prisoner's own doctor is seen as a one-off concession. It also occurs, especially in large penitentiary institutions, that the detainee does not have the assurance that he will always be treated by the same ward doctor. For this reason there could at least be provision for the figure of "a section doctor", therefore ensuring that the detainee sees a doctor who has some historical memory of his medical situation as well as a recognised responsibility towards him¹⁵³.

- *The inadequacy of the information to the patient and his relatives.* Deficiencies regarding communication and the relationship between the health staff/patient also exist "outside the prison walls" however in prison they

¹⁵¹ Dramatic cases reported during the expert auditions held by the guarantor of the Campania region. The example is cited of a paraplegic prisoner, in a wheelchair, in a cell with three other paraplegics, with a single guard to take care of all of them, with regard to cleanliness etc. And another prisoner who after surgery for spinal cord tumor is forced to walk with sticks and wear a collar because he cannot keep his neck straight. He needs hydrokinesitherapy, which of course is not feasible in prison.

¹⁵² It is the case, for example, of a terminally ill Belgian prisoner, serving a sentence in Sassari: he had asked to be allowed to die at home but died in prison in April 2013.

¹⁵³ This is a proposal made by the prisoners of the correctional facility of Padua.

have greater repercussions and contribute to the perception of “abandonment” of the detainee, all the more serious when the individual is suffering from an illness. As for the difficulty of family to obtain news about their relatives, these can have dramatic outcomes. One indication of the lack of dialogue with the medical staff is the dissatisfaction expressed by many detainees faced with the so-called prescription of generic drugs, which means that no time was given to provide the patient/detainee with sufficient information on the drug therapy. In other cases, there are complaints about no feedback to the patient as regards the results of clinical tests.

Lastly, the emergency of overcrowding should once again be reiterated: despite international indications and the guidelines of the healthcare reform in prisons recommending taking charge of the environmental and social aspects of health, the reform has so far failed to have a significant impact on these aspects. Overcrowding, with the highly harmful hygienic and psychological consequences, along with prison regimes (especially when held in custody) which compel to be in the prison cell for more than twenty hours per day, exacerbated by difficulties in accessing work and training activities constitute an emergency which has grown into a situation of dramatic normality in our country. On these aspects, so detrimental to the right to health, little has been heard from the voice of the competent health authorities.

6. Healthcare personnel: specific ethical aspects

Another aspect of the healthcare reform in prison is the administrative placement of healthcare personnel employed by the NHS and no longer by the Prison Administration. This step is a guarantee for the autonomy of the healthcare personnel. Autonomy is particularly valuable to doctors and the reform emphasises, even symbolically, the first duty of the physician to stand in defense of the well-being of the patient, fully independent from the prison administration. This passage, from “prison doctor” to “doctor tout court”, however, calls for cultural maturity, in order that doctors may consider themselves truly autonomous and at the service of the individual, without being improperly responsible for other requirements and viewpoints that they are not called on to represent; and which in fact they are called on to counteract “on the part of the patient”. This process of autonomy of the doctor is not totally complete. During the consultations of experts, it was repeatedly emphasised that the younger doctors who have experience of the NHS “outside the

prison walls”, better interpret their mandate; whereas a part of the doctors from the old prison health system are more likely to maintain the old role.

An indicator of insufficient acquisition of the spirit of the reform is the fact that doctors are often called upon to play two very different roles: their own as a therapist, and the one of the expert called on to judge the health of the detainee, in relation to the measures to be taken by the competent judicial or prison authority (see deferment of sentence for early release or incompatibility with imprisonment due to health conditions). It would be more appropriate for this judgment to be left to a doctor different from the actual doctor on the ward, so as to avoid to adversely affect the doctor-patient relationship¹⁵⁴. Moreover, this is the indication at international level. The intent of preserving the fiduciary mandate of the doctor towards the patient clearly emerges also in other measures recommended by the WHO. In particular:

- in the case of special detention schemes (in Italy, Art. 41bis, for example) and particular conditions of detention such as isolation, in which the administration wants to limit contact with the prisoner as far as possible, it is recommended that the healthcare personnel should always be able to visit prisoners, *and they should claim this right if it is denied*.

- again in the name of the ethical principle that the doctor is called to pursue the well-being of the patient, it is recommended that doctors should not lend themselves in any way to certifying that a prisoner is able to sustain isolation or any other form of punishment. In particular, isolation for disciplinary reasons, according to the WHO which has evidence related to the damage that this causes to health, so much so that the United Nations has called for its elimination¹⁵⁵. From the harmful results of isolation recorded on the health of prisoners, there has been identified a specific syndrome denominated (*Secure Housing Unit Syndrome*)¹⁵⁶.

¹⁵⁴ S. Antinarelli et al., *I rapporti tra sanità penitenziaria e Autorità giudiziaria*, in “Salute e Territorio”, September-October 2012.

¹⁵⁵ *Basic Principles for the Treatment of Prisoners*, Resolution 45/111 adopted by the General Assembly on 14 December 1990.

¹⁵⁶ In December 2007, a Group of 24 international experts promoted the Istanbul Declaration on the *Use and Effects of isolation in prison*, asking states to limit the isolation to truly exceptional cases and for very brief periods making recourse to it only as a last option. For a review of the literature on the effects on health of disciplinary isolation, see Sharon Shalev, the centre of Criminology at the University of Oxford (presentation at the *Network Meeting on Prison and Health cit.*).

7. Specific areas of intervention

Health data, computerised medical records and telemedicine

Computerised medical records are a decisive step forward for the practicability and timeliness of information regarding the health of all its citizens. This applies even more to those who are imprisoned, subject to transfers from one prison to another and from one region to another. At the moment, computerised medical records for prisoners exist only in Emilia Romagna and, on an experimental basis, in Tuscany. The remainder still relies on paper documentation, which accompanies the detainee in his transfers, often with great delay. Moreover, once again, there is the problem of reconciling organisation of the healthcare system on a regional basis, with the need to have data at national level. The regional medical record is inadequate for prison: instead, there needs to be a national healthcare dossier for the prisoner which collects from the computerised operational folders in use in the regions the essential information in order to reconstruct the clinical history of the detainee. The national medical file should therefore be constructed and managed by the Administrative Penitentiary Department on the basis of information obtained from the Regions and the Local health authorities. There has been reported a disconnection in this area between the tools of the APD, and the Health Service: the AFIS database (Automated Fingerprint Identification System) in use at the Administrative Penitentiary Department, which allows in every prison: quick reference to information about detainees, it already contains a “clinical diary”, which however is not utilised by healthcare personnel.

If a medical record is the perfect tool to ensure the continuity of the therapeutic relationship, it constitutes only the first step towards realising those forms of telemedicine which enable monitoring and specialist consultation at a distance through electronic submission of tests, images and data to centres of excellence, without having to face all the problems, with their associated costs and delays, transportation of prisoners or of doctors. There are, for example, the highly significant cases of Porto Azzurro and Regina Coeli. In the former case an agreement with the Department of Dermatology, of the Hospital of Livorno allows the transmission of high-resolution images of melanomas or other infections or skin lesions, as well as the related examinations and medical history reports, providing rapid and highly qualified therapeutic assistance. In the second case telemonitoring and specialistic

teleconsultation concerns cardiological care and it is achieved through a Convention with San Giovanni Hospital in Rome.

Telemedicine therefore offers undeniable advantages in terms of efficiency of service, increased safety and, once fully in operation, reduction of costs. Its implementation requires all the necessary investments to modernise facilities, from the introduction of broadband to the acquisition of appropriate equipment for the acquisition and transmission of data. It presupposes, in short, as has been pointed out several times in the course of this document, this change in mentality that compels the consideration of the prison sentence as an aspect, albeit dramatic and controversial, of the effort to adapt to the increase in civility of a technologically advanced society and not the ancestral remainder of an approximate management of suffering and marginalisation.

As it is now sadly only an abstract concern, it must be affirmed, even in the face of all the advantages offered by distance care through telemedicine, the right of every patient¹⁵⁷, and therefore of every prisoner, to a direct and personal relationship with the doctor. Telemedicine should be seen as the best possible accomplishment of this and not as an alternative model or its substitute.

Mental health

The area of mental health should be a priority in health planning in prisons, both because, as we have seen, it is one of the areas with a greater prevalence of disorders¹⁵⁸; and because the very condition of imprisonment itself is in a high mental risk index. This analysis is supported at international level in nine million people, detained all over the world, at least half of these suffer from personality disorders, while one million suffer from serious mental disorders such as psychosis and depression. Almost all the prisoners have experienced depression and stress symptoms¹⁵⁹.

The network of territorial services needs to take charge of people with mental health problems, following the principles of the healthcare reform

¹⁵⁷ “Ethics, health and new information technologies”, 21 April 2006.

¹⁵⁸ The abovementioned research of the Tuscany Regional Health Agency (2009) shows that 29% of prisoners have been diagnosed with a mental illness.

¹⁵⁹ WHO, 2007 cit., pp. 133-144.

itself: by targeting intervention to individual care projects, involving all the support resources available inside and outside prison; and with projects to assist social reintegration upon release. This requires not only a good provision of specialised personnel (bridging the shortage of psychologists mentioned above), but also taking on an approach to promote mental health, with an active control on the general conditions of life in prison. As pointed out by the WHO, “the presence of healthcare personnel does not in itself guarantee health”, let alone mental health. Again, the importance of ensuring acceptable environmental conditions, treatment according to the principles of humanity, respect for human rights is reiterated. The WHO gives an account of the most significant factors for the promotion of mental health, as is clear from research: firstly, assistance and services that facilitate self-promotion and guarantee respect for other people; secondly, satisfaction of the need to be appreciated and to be the object of care; thirdly, the opportunity to engage in activities and to have distractions¹⁶⁰. These outcomes also indicate general and simple measures to improve the prison regime: such as the opportunity to receive regular visits from family and friends or to have access to work or study activities. It is important, however, that these and other measures should be considered for their importance as protective factors for mental health, and be fully included in health programming in an active inter-institutional dialogue between the health authorities and the prison administration.

Recently, the prevention of SIB and suicide risk has become a specific and priority objective, by way of several acts: from the APD newsletter dated 25 November 2011 to promote reception and support staff at the time of entry into prison, to the State Regions agreement of 19 January 2012 “Guidelines for reducing the risk of self-harm and suicide of prisoners, internees and minors subjected to criminal detention measures”, to the three-year interregional project, supported by the Ministry of Health, for the testing of an operational model for prevention¹⁶¹.

¹⁶⁰ WHO, 2007, cit., p.138.

¹⁶¹ Collaboration Agreement of 29 August 2012 for the implementation of the project *the health status of the detainees in the penitentiary institutions of six Italian regions: an experimental model for monitoring of health status and the prevention of suicide attempts* (Veneto, Liguria, Umbria, Lazio, Campania and Tuscany as lead partner).

The NBC takes note of the efforts made at various levels of government to reduce the dramatic emergency and, in the wake of the information already provided in its Opinion of June 2010 (*Suicide in prison. Bioethical guidelines*) it recommends an approach that does not focus only on individual psychiatric risk factors, but it takes due account of the situational factors that can aggravate the stress of imprisonment, and, more generally, the risk involved in a prison environment that is not adequate or even that fails to respect the dignity and rights of individuals: as we have just seen, the WHO stands firm on this aspect.

This permits avoidance of “psychiatrisation” of the problem of suicide in prison, as well as the stigmatisation of people attempting to take their lives: with the risk of resorting to counterproductive measures, such as isolation of individuals and their exclusion from activities that take place in the penitentiary.

Along these lines, of active promotion of mental health, it is important that efforts to give greater attention to the moment of reception of newcomers should also be extended later on: essential services, such as early and continuous information about one’s legal situation, the connection with family and significant others outside prison, easy access to talks with psychologists, and in general to basic health services, are important protective factors; as well as a positive relational climate, where the detained person has the opportunity to have a supportive relationship with all the personnel that the prisoner comes into daily contact with. There are interesting pilot projects (for example, in Bollate-Milan-Florence and Sollicciano), creation of health desks in which health information to prisoners and the relationship with health services are managed by the detainees themselves, who have a significant operative role. These programs should be made more widespread.

As regards Judicial Psychiatric Hospitals, their being brought to an end is now at an advanced stage as started by the Prime Minister’s Decree of the 1st of April 2008, although the date for the final closure of JPHs was extended for one year in February 2013. In summary, the institution of acquittal for those considered not imputable on account of mental illness remains unchanged, so that they are subjected to security measures (or provisional security measures when they have not yet been judged): with the reform, those who have been acquitted, but declared dangerous (and therefore subjected to a security measure) will be taken charge of in therapeutic projects within the ter-

ritory arranged by special divisions of the Departments of Mental Health; or in the new psychiatric residential facilities, which should meet, in terms of size and functionality, the therapeutic purposes (but with external police control). Although the closure of JPHs is a positive innovation, important issues remain to be solved, such as the reference criteria, currently lacking, for the proper assignment of persons to the two types of taking in charge described above: the risk is that the majority of the acquitted may be simply destined to the new structures. Suitable thought should be given to these psychiatric residencies which the Regions are currently preparing to avoid the pressure for economies of scale leading to over-sized structures that are likely to recreate the typical conditions of the mental asylum, with a concentration of its population and distancing from services and context belonging.

Female detainees

In 2009, the WHO Europe and the UNODC published a document whose title contains in itself a line of action: “*Declaration on women’s health in prison: correcting gender inequity in prison health*”. In first place in the final recommendations is the creation of a criminal justice system that is gender-sensitive, that is, which takes into account the specific needs and circumstances of life of the female gender: for example, that considers the types of crime committed by women. Women are often convicted of petty crimes, in relation to which imprisonment has a disproportionate impact on their health (and that of their children, if they are mothers).

Coming to detention, there is a paradox: the greatly reduced numbers of females compared to males in detention (2,800 women out of 66 568)¹⁶², that does not appear to benefit women. Very often they are locked up in women’s sections of male prisons, organised for the needs of men, while there are few women’s prisons¹⁶³. Although the problem of overcrowding for women prisoners does not exist, in general, in male prisons there is less attention to the functioning of the women’s sections and there are fewer treatment services.

¹⁶² APD, data on the number of prisoners, to 30 September 2012.

¹⁶³ Women’s prisons are present only in Trani, Pozzuoli, Empoli, Rome Rebibbia Pontedecimo Genoa, Venezia Giudecca, while there are 64 women’s sections of male prisons. There is only one Clinical Centre for Women in Pisa.

Imprisonment appears to have a greater impact on the suffering of women, not only because the stigma of imprisonment is still heavier; but also because the control of time and especially of space in daily life is an important dimension to the well-being of women, so this loss is felt by women more dramatically.

The treatment of women is linked to the concept of female transgression: crime tends to be seen as a “mistake” even before an offense: hence the shift towards educational/correctional paternalism. Women are seen as “weak” in a manner not dissimilar from minors: less (intentional) “hardness” but with the risk of greater arbitrariness and fewer rights: the logic of the reformatory rather than of the prison, which however may lead to greater suffering and feelings of *helplessness*¹⁶⁴.

The female network of emotional relationships, usually richer than that of males, may constitute a factor for protection and support. Often, however, it turns into the very opposite, because women suffer separation more acutely: and because little is done in prison to facilitate the maintenance and the assiduity of contacts with the outside.

In addition, one should not overlook the presence of children under three years old who live in prison with their mothers. Currently in Italy there are about 50 children locked up. The law provides for house arrest for mothers with children that are under three years of age. This, however, is not applicable when the female prisoners have no residency or are repeat offenders. Most of the children detained are the children of nomads. The risks and harmful effects are serious: illness, psychological trauma, poor language skills, etc.

In theory, the imprisonment of children should end by virtue of the Law of 21.04.2011, No. 62 (Provisions relating to detained mothers), which provides for mitigated custody in ICAMs (Institutes for the mitigated custody of detained mothers), more liveable penitentiary institutions, or in secure shelter homes. Under this legislation by January 2014, all mothers of children aged three to six years should be transferred. However, it is easy to predict that this is not likely to happen because there are at present only two ICAMs, one in Milan and one in Genoa and another is being built in the

¹⁶⁴ Cf. E. Campelli, F. Faccioli, V. Giordano, T. Pitch, *Donne in carcere*, Feltrinelli, Milan, 1992.

Lazio Region. However, there are also influential opinions that are contrary to the ICAMs on the assumption that no child should enter the door of a prison. Hence, the desire for an alternative solution as represented by shelter homes, where it would be possible to house the children until the age of six and to reconstruct the family network with the siblings.

Addiction to illegal substances

Despite the declared intention of legislators from 1990 onwards to avoid imprisonment for drug addicts, the percentage of people addicted to illegal substances of the total prison population still remains high. In recent years, this is even on the rise. This applies to admissions to prison over the whole year (28.6% in 2005, compared to 32.4% in 2012), but also for the attendance calculated on any given day of the year (37, 31/12/2006 5%, compared to 38.4% 31/12/2012)¹⁶⁵.

The area of drug addiction passed under the National Health Service in 2002, in advance of the passage of general responsibilities, as an experimental area of the healthcare reform in prisons. This has led to improvements in some critical phases of the management of drug addiction in prison: for example, the treatment of the crises that may be suffered by opiate users is now a common intervention of care. These interventions are important, since the admission procedures may involve even lengthy periods (arrest, validation of the arrest, transfer to prison, registration)¹⁶⁶. The presence of the SERT should also be designed to prepare treatment plans to facilitate the access of people with addictions towards alternative measures, such as special custody for drug addicts.

Nevertheless, there remain critical issues, as reported also at an international level. The European Monitoring Centre for Drugs and Drug Addiction complains about the delay in adaptation in prison to the treatment standards of the services outside prison (a difference of about 8/9 years). A recent review of 21 studies of programs with methadone maintenance in

¹⁶⁵ The source is the APD, Office of development and management of automated information system-Statistics Section. Most of the people with addictions are in prison for violating the anti-drug legislation itself, or for drug related offenses.

¹⁶⁶ Cf. S. Libianchi et al., *La tossicodipendenza e il carcere*, in "Salute e Territorio", No. 194, 2012, pp. 287 et seq.

prison reported benefits similar to those seen in the programs in the country's territory, such as: the ability to attract people in treatment, reduction of the use of illicit opiates, the reduction of risk behaviors (especially the promiscuous use of material for injection). Most importantly, it reduces the (high) risk of a drug overdose in the period immediately following release¹⁶⁷. It also points out the importance of continuity of treatment in services on national territory, after release.

The European Observatory examines in various European countries, the coverage of methadone programs in prison, i.e. the percentage of people receiving treatment over the total number of those estimated to need it: Italy is placed in the category "limited coverage" estimating that the number of those treated with methadone corresponds to less than half of the people who could benefit from it¹⁶⁸.

Communicable diseases: the HIV virus

As previously reported, the HIV virus is one of the transmissible infections that cause most concern, both because the prevalence is highest among the prison population, and for the risk of stigmatisation faced by people with this infection. International organisations insist on both prevention and treatment so much so that a document signed by all relevant UN agencies (UNODC, ILO, UNDP, WHO, UNAIDS) was recently published¹⁶⁹. In the text, after having complained that only a few countries in the world provide appropriate programs, it recommends a comprehensive package of 15 key interventions: 1) information and education on HIV, hepatitis, and sexually transmitted diseases; 2) availability of condoms to prisoners (discretely); 3) Prevention of sexual violence (in particular protecting the vulnerable such

¹⁶⁷ D. Hedrich et al., *The effectiveness of opioid maintenance treatment in prison settings: a systematic review*, in "Addiction", 107 (3), 2012, pp. 501 et seq.

¹⁶⁸ EMCDDA, *Prisons and drugs in Europe: the problem and responses*, Selected Issue, 2012, pp. 22-23.

¹⁶⁹ United Nations Office on Drugs and Crime, the International Labour Organization, United Nations Development Programme, World Health Organization, UNAIDS, *HIV prevention, treatment and care in prisons and other closed settings in: a comprehensive package of interventions*, 2012. Urgency for HIV/AIDS is also confirmed in other documents. See WHO, 2007, cit., p. 51; UNODC, UNAIDS, WHO, 2006 *HIV/AIDS prevention, care, treatment and support in prison settings: a framework for an effective national response*.

as people with a different sexual orientation and young people; 4) Treatment of drug addiction including opioid replacement therapy; 5) Availability in a confidential manner of sterile material for injection to drug users; 6) Prevention of transmission that can occur through infected dental and medical supplies; 7) Prevention of transmission that can occur through tattooing; 8) Post Exposure Prophylaxis in situations of possible contagion; 9) Easy access to voluntary HIV testing and counselling; 10) Treatment for HIV including antiretroviral therapy; 11) Prevention, diagnosis and treatment of tuberculosis (considered the high percentage of HIV-TB co-morbidity; 12) Prevention of mother-to-child transmission; 13) Prevention and treatment of sexually transmitted infections; 14) Vaccination, diagnosis and treatment of viral hepatitis (including hepatitis B vaccination for all, for hepatitis A for those at risk, and prevention/treatment for hepatitis B and C); 15) Protection of personnel (which should receive information, education and training from healthcare personnel, in order to carry out their work tasks safely).

8. Migrants and Centres for Identification and Expulsion

Foreigners account for a substantial proportion of the prison population, about 36%. There are various nationalities, among which people from Africa and Eastern Europe stand out. Many do not possess identification documents and this leads to several critical problems, including the difficulty in establishing the age of those who run into the law, and of importance for the protection of minors.

Detention entails for both the male and female foreigner, especially those without a residence permit and valid identification document, many additional problems and suffering, including¹⁷⁰:

- A more difficult communication with the personnel working in institutions, due to language problems but also because of cultural barriers impeding the full understanding of different roles;

- The lack of family ties or relationships in the territory and the difficulty in maintaining relationships at a distance: phone calls to the family are often hampered by the economic hardship of the detainee and the difficulty of inspection on telephone subscriptions in foreign countries;

¹⁷⁰ S. Libianchi, *La detenzione dello straniero*, in "Salute e territorio", 194, 2012, pp. 293 et seq.

- The internal work is not very accessible due to lack of documents and tax code number;

- Education and professional courses are designed to address the needs of Italians;

- Frequent homelessness and social ties within the territory narrows the possibility of obtaining benefits and take advantage of alternative measures to prison. In addition, cultural differences involve a different idea of the body, of its care, as well as the very concept of health.

To ensure that foreigners are able to exercise the same rights, the constant and not sporadic presence in prisons of a cultural mediation service is a priority. The cultural mediation project “Health without flags”, launched at the end of 2012, to promote the healthcare integration of detained foreigners through full and informed access to the NHS, even during the period of detention. The project involves nine institutes with a greater presence of foreigners, including Rome-Rebibbia and Milan-Opera.

Foreigners without documents who have not been identified during the period of imprisonment are interned in the ***Centres for Identification and Expulsion***.

In these centres the right to health of the internees is subject to such limitations as to question the use of the term “right”.

In the first place the centres are located in inappropriate containers strongly lacking in terms of hygiene. There is a concentration of subjects of different and heterogeneous origin, many of them being particularly vulnerable: such as persons seeking refugee status and the victims of trafficking, who are likely to be locked up along with their enforcers. Assistance in the centres is not the responsibility of the NHS, instead it is provided by the managing body of the Centre. In most cases, it is basic healthcare calibrated on the previous legislation which allowed detention for not over thirty days. After extension of this period to six months, healthcare has become completely inadequate and there are serious cases recorded of persons not treated properly. In addition, there are great problems in obtaining the clinical documentation in the passage from prison to the CIE.

To these difficulties, there must be added the adverse psychological aspects: internees see this period as an additional punishment to the one already served, and moreover with fewer guarantees (they do not know how

long they will remain in the Centre) and with fewer opportunities to carry out some activities.

Prompt action is necessary, with a number of urgent and immediate measures:

- The CIE should be closed or at least brought back to their original function as an exceptional measure, as required by the EU Directive, restoring as an ordinary measure assisted voluntary return (financed by a special European fund)¹⁷¹;

- The NHS must take charge of the CIE or at least there should be immediate activation of agreements and conventions in this regard. Not only should adequate services be provided, there should also be a check on the state of premises, the adaptation of services and hygienic conditions, adaptation of lifestyle to the requirements which respect the dignity of persons;

- Identification must take place during the period of detention;

- Vulnerable groups must be protected, including the victims of trafficking, their regularisation should take place for humanitarian reasons.

Recommendations

- The NBC recommends to the competent institutions that the right to health of prisoners is to be understood in the full sense, in order to achieve an effective rebalancing in the levels of health inside and outside the prison walls, way beyond the guarantee of equality of access to healthcare services.

- The NBC reminds that the foundation of health of the prisoner is being treated with dignity and respect, in full observance of fundamental human rights. These include the right to receive treatment outside prison when detention exacerbates the suffering of infirmity to intolerable limits.

- The Committee points out that healthcare reform is not limited to the transfer of authority from the prison administration to the health administration. In keeping with a comprehensive approach to health, the health authorities must take full charge of control of the hygienic conditions of the institutions, the state of the cells and services, the living conditions of pris-

¹⁷¹ A. Barbieri et al., *Arcipelago CIE. Indagine sui centri di identificazione ed espulsione italiani*, Medici per i Diritti Umani, May 2013. The MEDU survey was conducted in centers of Bari, Bologna, Caltanissetta, Crotona, Gorizia, Lamezia Terme, Modena, Rome, Turin, Trapani Milo.

oners, tolerability of the prison regime. The ruling of the European Court of Human Rights on January 8, 2013, which judged life in overcrowded Italian cells as “inhuman and degrading treatment” indicates that the reform is still far from achieving its objectives.

- The NBC noted that some aspects of the healthcare system provided on a regional basis should be modified, if one wants to offer detainees equal opportunities in healthcare services. In particular, penitentiary administrations and the Regions need to work to *launch national computerised medical records* as soon as possible, which can follow the prisoner in real time when transferred from region to region; to ensure continuity of care when passing from one prison to another, even in the presence of varying levels of care from region to region.

- The NBC calls for the immediate application of measures for those aspects in which the most serious inequalities persist or where equal opportunities in accessing services are not met: insufficient promptness in emergency intervention, delays in specialist consultations and in the planning of interventions in outside hospitals, inadequate services to meet the specific needs of the prison population.

- The NBC recommends key areas of intervention, particularly with regard to mental health and the prevention of suicide and self harming, the prevention of HIV and other communicable diseases. More attention should be paid to the rights and needs of women prisoners, as part of a gender-sensitive criminal justice system.

- The NBC invites the NHS in its subdivisions within the different regions to immediately take charge of the serious health situation and living conditions in the Centres for Identification and Expulsion, pending more far-reaching measures to decide the fate of these structures and solve the spectrum of problems related to persons without a passport.

- The NBC also recommends great attention to ensure that an area as delicate as prison, which requires every effort to reach an acceptable standard of living, does not, on the contrary, have to suffer from the reduction in resources.

Presidenza del Consiglio dei Ministri



**CONCERNING BIOETHICAL ISSUES RAISED BY
ARTICLE 13, LAW NO. 96 OF AUGUST 6, 2013,
*“Criteria in view of a Governmental Decree
for the fulfilment of Directive 2010/63/EU
of the European Parliament and of the Council
of September 22, 2010”***

**Response to the query submitted
to the National Bioethics Committee
by Senator Prof. Elena Cattaneo**

24 January 2014

Presentation

The NBC with this document responds to a query submitted by Senator Elena Cattaneo concerning the bioethical issues raised by the recent debate on animal experimentation, as a result of the Law August 6, 2013, n. 96, art. 13, which transposes Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010.

The document was approved by Profs. Carlo Caltagirone, Stefano Canestrari, Cinzia Caporale, Carlo Casonato, Lorenzo d'Avack, Francesco D'Agostino, Antonio Da Re, Mario De Curtis, Riccardo Di Segni, Carlo Flamigni, Paola Frati, Silvio Garattini, Assunta Morresi, Demetrio Neri, Andrea Nicolussi, Laura Palazzani, Massimo Sargiacomo, Monica Toraldo di Francia e Giancarlo Umani Ronchi.

Profs. Salvatore Amato, Marianna Gensabella e Grazia Zuffa abstained from voting.

Prof. Luisella Battaglia voted against.

Profs. Bruno Dallapiccola e Lucetta Scaraffia both absent from the session subsequently expressed their approval.

Dr. Carla Bernasconi, a delegate of the President of the National Federation of Italian Veterinarians; Prof. Enrico Garaci, President of the Board of the National Institute of Health; Dr. Carlo Petrini, a delegate of the President of the National Institute of Health, present at the discussion as ex officio members of the Committee, without voting rights pursuant to the Decree of the President of the Council of 27 September 2013, invited by the President to express their views, declared that they were in favor of the motion.

Prof. Rosaria Conte, delegated by the President of the CNR, absent from the meeting, subsequently approved the motion.

Preamble

The Parliament is engaged in the transposition of the new European Directive 2010/63/EU on the protection of animals used for scientific purposes, with the enactment of Law 6 August 2013, n. 96, Art. 13 “*Criteria for delegation to the Government for the transposition of Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010.*”

This Italian legislation has given rise to an extensive and important debate among the general public, the media, the research community and within political institutions. The debate on several occasions has become harsh and misleading, with the risk of endorsing false ideas and creating disaffection towards scientific research, its methodology and the bioethical reflection concerned.

The Committee has intervened several times on the issue of animal testing, and refers in particular to the Opinion: *Alternative methods, ethics committees and conscientious objection to animal testing, 2009*¹⁷².

The Committee intends to make some further considerations on this subject, taking into account the query that it has been put.

From a scientific and epistemological standpoint, there must be reiteration of the centrality of experimentation on animals as a cognitive method for studying living organisms and in particular humans. The progress of knowledge advances through the use of models, and those involving animals occupy a prominent place. The question to ask oneself is which models and which research strategies to adopt each time, and how to maximise the scientific result, in accordance with the regulations.

It should be noted that fundamental scientific discoveries on the primary functions of the human body are historically due to the experimentation conducted on animals, as well as some basic biomedical innovations such as vaccines, blood transfusions, anesthesia, transplants and in general surgical procedures, extracorporeal circulation, dialysis, pacemaker, magnetic resonance imaging, gene therapy, the use of stem cells for degenerative diseases and, of course, the discovery and development of drugs and treatments for the very large part of human pathologies.

¹⁷² Other Opinions of the Committee on the subject: *Bioethical problems concerning the use of animals in activities linked to human health and well-being*, 2005; *Bioethics and veterinary science, animal well-being and human health*, 2001; *Animal testing and health of living beings*, 1997.

Indispensable, above all, has been and will be the contribution made to basic knowledge, including the knowledge we set at the foundation of ethical sensitivity towards animals and which is due to scientific developments and their results.

From an ethical point of view, as stated by the Committee, it is necessary to reconcile, in a balanced and shared manner, different good, each good being worthy of protection, even if of a different order, such as health and human well-being, the promotion of scientific research, the reduction of suffering for the animals subjected to experimentation and their same well-being and interests to receive care, respect for the intimate beliefs of individual researchers in relation to the experimentation. We must always keep in mind that although animal testing is scientifically grounded and useful, it must be a constant exercise of mediation between different values. The privileged moral status of man, and the centrality of his interests and of primary human good - however it may be founded, whether according to beliefs and metaphysical reasons or the recognition that there is an evolutionary rationale for our finding it beneficial and adaptive to assign a different moral value to other living beings on the basis of predispositions that are natural to us and which have a biological basis - this cannot make us forget that life in all its dimensions has an immense bioethical value. Consequently animal life deserves attention and respect.

The infliction of unnecessary and disproportionate suffering to animals is therefore unacceptable, particularly if strategies exist which can be fostered to minimise or abolish it. Therefore, animals should always be treated as sentient beings and their use in scientific procedures should be restricted to areas which truly make science advance and produce essential good such as health for humans as well as for animals themselves.

Considerations

Accordingly, the Committee:

1. acknowledges the need for scientific use of animals to test drugs and treatments aimed at the advancement of knowledge and the discovery of therapies for human health as well as animal health;
2. is in favor of limiting the use of animals for experiments (reducing the number) and favourable to the use of animal experimentation only if scientifically justified and relevant, with protocols based on criteria of propor-

tionality and the reduction of suffering, to be examined by independent ethics committees;

3. calls for an increase in the research of so-called alternative methodologies and the use of complementary methods to animal testing (already established practice in all research laboratories);

4. points out that, although the results obtained from animal testing are not automatically applicable to humans, the scientific community agrees that these results are essential in order to prevent testing directly on humans;

5. reiterates its being in favor of animal testing only insofar as it is necessary for human health and to increase knowledge even in the field of animal health, in the belief that the importance of research and the illicitness of conducting experimentation directly on humans regardless of testing on animals to be a shared fact in bioethics and international biolaw;

6. shares the bioethical principles contained in *Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for research purposes*;

7. stresses that the provisions of Law 6 August 2013, n. 96, aimed at ensuring more extensive protection of animals in relation to the *Directive*, are bioethically questionable; in fact, they introduce additional restrictions giving rise to problems regarding the correct juridical application of that same *Directive*. More precisely, the bioethically controversial aspect of certain points must be emphasised:

- regarding the prohibition of xenotransplantation (i.e. transplantation of organs and tissues in different species), the Committee believes that it is useful experimentation with reference to the transplantation of organs and tissues among different animal species (e.g. for the study of anti-rejection drugs, of tumors, etc.);

- regarding the prohibition of research on the substances of drug abuse, the Committee believes that such experimentation on animals would be of considerable scientific importance, especially today faced with the spread of new drugs sold on the internet whose effects on humans are not yet known;

- regarding the prohibition on breeding on national territory of dogs, cats and non-human primates for experimentation, the Committee considers that this prohibition impedes Italian research within the framework of European research and inevitably entails the importation of animals, causing

unavoidable discomfort for the same animals as well as additional costs for research.

Recommendations

The Committee makes a series of recommendations:

1. to proceed quickly to transpose the European Directive 2010/63/EU on the protection of animals for scientific purposes, without creating conditions that marginalise the Italian research system, which is already fragile, and without betraying the goal of approximation of national legislation pursued by new EU laws;

2. to provide for simplification of the Italian regulatory framework and verification of regulatory coherence, in order to guarantee effective protection of animals;

3. to valorise Ethics Committees for animal testing, in line with the new European Directive, ensuring their independence and impartiality and third party status;

4. to allow for the effective exercise of the right to conscientious objection to animal testing in accordance with the law;

5. to give effect to Circular No. 6 of 14 May 2001 of the Minister of Health, in application of Legislative Decree no. Jan. 27, 1992, n. 116, introducing the principle of so-called adoption of guinea pigs;

6. to promote within the scientific community a culture for ever greater attention to the problems associated with the use of animals for scientific purposes, urging the creativity of researchers aimed also at mitigating the impact of testing on sentient beings.

Lastly, the Committee emphasises, the importance of ensuring greater accuracy of the news and comments in the non-specialist press and makes an appeal to the media to help prevent the spread of radicalism and fanaticism when discussing about science, for example, by not using misleading terms such as vivisection, and vice versa by promoting internal values to science such as recourse to logic and constant verification of the facts, respect for the requirements of objectivity, rigor and clarity of argument and intellectual honesty.

ATTACHMENT: Letter of request from Senator Prof. Elena Cattaneo to the National Bioethics Committee

Rome, 22 January 2014

Senate of the Republic
Sen. Prof. Elena Cattaneo
12th Health and Hygiene Commission

To the President of the National Bioethics Committee
Prof. Francesco Paolo Casavola

Dear President,

scientific experimentation conducted on animals and the related bioethical profiles are currently at the centre of a heated public debate and Parliamentary attention engaged in the transposition of the new European Directive 2010/63/EU.

However, in my opinion, the debate does not present a sufficient level of in-depth theoretical study and this is likely to create a distorted picture of scientific enterprise among the general public.

I am writing to you as I think the National Bioethics Committee with its diversity of members in terms of subjects and represented authority can and should strongly contribute to a balanced debate starting from facts of science to integrate the various philosophical, historical and moral components, and reaching what I consider may be a useful, even synthetic pronouncement containing guidance on the subject and indications of an ethical nature of general valence.

Trusting in your understanding of the problem,
Best regards

Prof. Elena Cattaneo

Presidenza del Consiglio dei Ministri



LIFESTYLES AND HEALTH PROTECTION

20 March 2014

Presentation

The NBC has intervened several times on the issue of health in previous documents, examining the series of factors which affect it and emphasising how, in addition to biological data, health also depends on resources such as education, work conditions, the housing situation, a healthy environment and behaviours as well as individual choices.

In recognition of the close interweaving of all these factors, the NBC has sought, in this Opinion, to dwell in particular on the bond between each person with their own health and collective responsibility.

Maintaining an efficient health service aimed at as many users as possible is in the interests of all citizens, but it also requires personal commitment to contribute as far as possible, to the maintenance of one's own health.

Starting with a brief description of the current situation, the document highlights the importance and the connection between the right to health of citizens and the duty of social solidarity.

Recalling the different paths of social and health policies, the Committee stresses the importance of a wide cultural activity that sets in motion the whole of society through various levels of intervention: educational (regarding school and family), social (providing information and training) and State.

The final recommendations make explicit some suggestions aimed at finding an effective synergy between the responsibility of individuals for their own health and the State's responsibility to protect health, which is recognised as a fundamental right of every person.

The document was prepared by Prof. Silvio Garattini, coordinator of the working group.

The group had already begun work during the previous mandate of the NBC, but not having been able to complete the debate, work was resumed in November 2013.

Written contributions were received from Professors Lorenzo d'Avack and Laura Palazzani: the interventions of Professors Carlo Casonato, Demetrio Neri, Andrea Nicolussi, Massimo Sargiacomo served to integrate the text.

The document was approved unanimously by those present, with votes in favor by Profs. Salvatore Amato, Luisella Battaglia, Carlo Caltagirone, Stefano Canestrari, Carlo Casonato, Francesco D'Agostino, Bruno Dallapiccola, Antonio Da Re, Lorenzo d'Avack, Mario De Curtis, Riccardo Di Segni,

Silvio Garattini, Assunta Morresi, Demetrio Neri, Andrea Nicolussi, Laura Palazzani, Rodolfo Proietti, Massimo Sargiacomo, Monica Toraldo di Francia.

Profs. Paola Frati, Marianna Gensabella, Lucetta Scaraffia, Giancarlo Umani Ronchi, absent from the plenary session subsequently expressed their support.

The ex officio members present (not entitled to vote) Dr. Paola Bernasconi, Dr. Anna Teresa Palamara and Dr. Carlo Petrini also expressed their support.

The President
Prof. Francesco Paolo Casavola

Preamble

A series of epidemiological studies has established with a high level of reliability that there is a correlation between certain lifestyles and the presence of a wide spectrum of diseases¹⁷³: from cardiovascular diseases to cancer.

Medicine has developed a series of rules that are the basis of primary prevention of diseases.

The term “primary prevention” refers to the adoption of actions and behaviours intended to prevent or reduce the occurrence and development of diseases in order to promote both individual and community health¹⁷⁴.

In Italy, as in other countries, interventions to protect health are carried out by the National Health Service (NHS) and the Regional Health Systems (RHS) which operate ideally according to the rules of universality, equity and gratuity. However since the resources of the NHS and RHS are not infinite, but tend to become insufficient due to the ever-increasing demands on the health system in terms of quantity and quality¹⁷⁵, as a result the sustainability of the NHS and RHS depend on and will depend on a strong commitment to promoting primary prevention as far as possible in order to reduce the number, the incidence and the severity of diseases, including those of a prenatal origin and promote health.

In previous documents, the NBC has examined the series of factors which affect health and pointed out that, in addition to biological factors, the achievement and maintenance of “possible health” depends on resources such as education, work conditions, housing situation, a healthy environment, behaviours and individual choices.

While recognising the close interweaving of all these factors, and their mutual influence, in this document, the NBC intends to focus on the last

¹⁷³ It refers, among others, to: S. Lim et al., *A comparative risk assessment of burden of disease and injury attributable to 67 risk factors clusters in 21 regions, 1999-2010: a systematic analysis for Global Burden of Disease Study 2010*, “Lancet”, 2012, 380, pp. 2224-60; M. Ezzati et al. (eds.), *Global and Regional Burden of Disease Attributable to Selected Major Risk Factors*, Volume 1, Geneva: World Health Organizations, 2010.

¹⁷⁴ Secondary prevention refers to early diagnosis of a disease; Tertiary prevention covers all therapeutic treatments (prevention of complications, relapses and death).

¹⁷⁵ See the NBC reference documents, dedicated to the issue of the distribution of healthcare resources: *Ethics, health care system and resources* (1998) and *Bioethical guidelines for equal access to healthcare* (2001).

factor, highlighting and stressing the responsibility of each person for their own health in two respects. The first is the responsibility one has towards oneself: health is a condition which offers the possibility to fully express one's personality and the prevention of the proportion of health risk factors attributable to modifiable individual behaviours produces a personal advantage, even in terms of the avoidance of suffering. The second aspect is that of collective responsibility: with limited resources, the maintenance of an efficient health service aimed at the greatest possible number of citizens is in the interests of all citizens and must therefore be able to rely on the personal commitment of individuals to contribute as far as possible, to maintaining their own health.

For this reason "lifestyle" deserves consideration not only with reference to the person, but also to the significant social repercussions which indirectly have an impact on the person.

This aspect comes under the more general problem of the ethics of health that involves adults and minors, the healthy and the sick, parents, mass media and public facilities from the dual perspective of the individual citizen and the community in which each one of us is a part, as both an active and passive subject.

It is important that in addition to the lifestyle habits that lead to addiction, including the use of drugs and tobacco¹⁷⁶ and alcohol abuse, often involving young people with psychological situations or personal problems, there should also be attention to eating habits dictated by social contexts and meanings that pay little attention to personal health or the health of others.

If in the first case, a complex job of re-education and elimination of the addiction is necessary, even with the help of the appropriate health and social services; in the second, the strategies to be adopted to make people aware of the negative consequences of their way of life, must be strongly oriented towards constant and accurate information and education¹⁷⁷.

¹⁷⁶ On this issue, see the previous NBC Opinion, *Tobacco Use* (2003).

¹⁷⁷ It is estimated that in 2010, tobacco was responsible for the deaths of 6.3 million people in the world, alcohol of approximately 4.9 million deaths. Tobacco and alcohol together account for over 12% of the global burden of disease and approximately 18% of total mortality per year. In terms of mortality, there is a smaller association with licit drugs compared with illicit drugs: opiates, cocaine, amphetamines, ketamine and cannabis. Another important factor for the disease is the consumption of foods

Ethical principles and proposed action

The Committee within the context of pluralistic debate and its implications with respect to the subject dealt with herein limits itself to highlight some problematic elements and to put forward some recommendations.

An individualistic approach which exclusively entrusts to the free market and subjective self-determination the decisions concerning the distribution of health resources and decisions regarding care must be avoided, as is to be avoided a concept of healthcare which sees the obligation of the State to deal with every necessity and guarantee each solution relating to health only on the collective level. Both perspectives - the individualistic and collectivistic one - do not consider the moral element which the Committee wishes to stress as central: the right/duty to urge all citizens to responsibly calculate the costs of their choices on health.

high in energy value, including drinks high in sugar, instead of foods with low energy value as vegetables and fruit. Excessive caloric intake results in overweight and obesity in children and adults with a consequent tendency to develop diabetes, hypertension, cardiovascular disease, stroke and cancer. Even a lot of osteoarthritis and skeletal fragility of the third age are caused by excess weight, which in turn is affected, equal to caloric intake, by the quantity of physical exercise. Exercise is extremely important for its ability to avoid being overweight, to increase blood circulation and prevent dementia. Obesity and its pathological consequences cause in the world each year about 18 million deaths 9.4 million due to hypertension (stroke and myocardial infarction), 3.4 million due to obesity, 3.4 million to diabetes and 2 million to hypercholesterolemia. Equally important is the prevention of transmission of infectious disease which occurs both with lifestyle habits that involve attention to hygiene to protect one's own health and that of others, and through adhesion to vaccination if existent. Greater knowledge of communicable diseases, with particular attention to those transmitted sexually is desirable. Among infectious diseases, caused by sexual promiscuity, there is still concern over the incidence of AIDS induced by HIV. For many infectious diseases, from bacteria and viruses the use of vaccinations has already led to remarkable results. In fact there are now rare cases of diphtheria, measles, and whooping cough; vaccination for smallpox was abolished, while there are very few cases of polio. Recently, vaccination against hepatitis B virus has allowed us to decrease the incidence and vaccination against human papilloma virus (accompanied by an adequate information campaign on the risks associated with the contraction of sexual infections) which should decrease the incidence of cancer of the cervix. From this simple and summarised information it seems clear what should be the "lifestyle" that can reduce the burden of disease and mortality: the abolition of tobacco and illicit drugs, drastic reduction of alcohol consumption, preference for vegetable and fruit compared to high energy food and drinks (fast-food and soft-drinks), moderate exercise and adequate information / sex education. If these rules were to be followed by the great majority of citizens, the NHS would diminish the magnitude of its interventions and could always use for the benefit of sick patients the saved economic resources, resulting in an improvement of individual and collective health.

Certainly, although the State should not impose paradigms of health to people who have different conceptions of health as a good¹⁷⁸, it is one of its duties to ensure, through law, measures for assistance and prevention and with the same care, the conditions for survival and health of citizens, urging them to realise that the right to health cannot be separate from the duty of social solidarity as provided by our Constitution, in general by art. 2 and, with regard to the protection of health by art. 32. The placing of art. 32 within the context of ‘ethical and social relations’, is already significant. In addition, the right to (protection of) health is recognised in that article both as “a fundamental right of the individual” and as “a collective interest”.

It is the duty of social solidarity that justifies attention to the consequences of one’s behaviour. In addition to this, it is important for the citizen to be aware of the fact that a statement of reasons for exclusion, albeit non-discriminatory, from one’s right to care can be given by objective clinical considerations stemming from behaviours and lifestyles which hinder effective treatment and which, however, do not guarantee adherence to therapy (as in the case of alcoholics on the list for a liver transplant or obese people on the list for a heart transplant).

Faced with these general considerations, it is possible to identify certain actions, both collective and personal, that are ethically shared, these actions are capable of helping to encourage improvements in the conditions of individual and public health.

Faced with the need to improve health through primary prevention, history and previous experiences in various countries indicate various possible paths. A first is to operate on the manufacturers of alcohol, tobacco and high-energy foods through “moral suasion” or the adoption of specific tax strategies; a second is represented by a public-private pact in which the necessary changes are gradually achieved; a third consists in making certain behaviours desirable through a strategy that may change the context (informative, for example) in which individuals adopt their own

¹⁷⁸ Already in another document, the NBC noted that “Such a choice might bring to bear on human tragedies, in which it is always very difficult to assess subjective responsibility, a ruthless judgment, in stark contrast to every criterion of solidarity” NBC *Bioethical guidelines*, cit., p. 35.

choices¹⁷⁹; another path is to operate through public imposition by law of the lifestyles considered appropriate for health.

The various ways are not mutually exclusive and do not cover all aspects of the problem which requires broader cultural action that sets in motion the whole of society through various levels of intervention.

1. It is scientifically proven that among environmental factors, good diet and nutritional balance is fundamental from the early stages of a child's life in order to determine present and future health. Good pediatric indications can construct a proper diet that takes into account the different stages of growth, introducing all essential nutrients and avoiding the risk of a repetitive diet or one that is aligned with that of the family, which is often a root cause of the problems of overweight. This also implies the need to provide parents with more information on the implications that nutrition in the first years of life can have on health in adulthood. It is always a part of the educational duties of parents to provide an example of healthy habits by creating awareness in their children early on regarding the damage caused through smoking, alcohol and other drugs and encouraging cultural and sporting interests. Similarly, it is important for education in primary prevention to continue at various scholastic levels. The example of teachers is certainly fundamental but it is also important that the rules regarding lifestyles should be proposed through education programs specifically aimed at acquiring knowledge of drugs and eating habits, but also taking cue from the opportunities arising from other teachings and occasions of the daily news. The school canteen is another important opportunity to put teaching into practice.

2. The social level of intervention is very important and must be in tune with the programs for primary prevention. A high level of participation by people having an important social role and visibility is required. First of all,

¹⁷⁹ The reference is to the so-called strategies of nudging in which individual adoption of specific virtuous behaviours is encouraged through the modulation of the characteristics of decision-making context. Intended in terms of "liberal paternalism", this approach pays special attention to behavioural sciences and to profiles which are often irrational at the basis of choices. See R.H. Thaler, R. Sunstein, *Nudge: Improving Decisions about Health, Wealth, and Happiness*, Yale University Press, 2008; finally, M. Quigley, *Nudging for Health: On Public Policy and Designing Choice Architecture*, in "Medical Law Review", 2013, n. 21, pp. 588-621.

doctors themselves who have a considerable influence on the behaviour of their patients: medical boards should be the main promoters of the information regarding primary prevention. Not to be overlooked is the influence which can be exerted, especially on young people, by those who have reached success, for example singers, athletes, entertainers. They can act as a “testimonial” through example, but also by avoiding taking part in publicity related to products contrary to the principles of primary prevention. Cinema, theatre, television and, more generally, the mass media should be careful not to advertise, directly or indirectly, products such as cigarettes or alcohol.

3. The State must maintain and increase strict monitoring on the quality of the food products in circulation in the country, even in relation to the country of origin. As regards certain addictive substances the State, as has already been said, undoubtedly has a conflict of interest, by its collecting taxes on the one hand and on the other paying for the damage caused by those taxed products. However, there can be no doubt about the priority of the health of citizens over other interests.

With regard to tobacco in Italy there has been in recent years a considerable reduction of anti-smoking propaganda: we must continue along the line that has banned smoking in public places, extending the ban to parks, stadiums as well as outdoor places, such as restaurants and all places where there is proximity of people. In addition, as has been shown by many studies, there may be a reduction in the number of smokers by raising the price of cigarettes. At the European level it is important to discourage the production of tobacco by eliminating the existing economic incentives. In Italy, several projects have been funded to reduce smoking, and the Ministry itself has started a program “Smoke-free Ministry”¹⁸⁰. The number of smokers dropped following the introduction of the so-called smoke-free law 3/2003, today it has remained virtually the same (22-23%; these values are e.g. above those of the United Kingdom and Sweden). Lastly, the NHS and the RHS should investigate the possibility of providing smokers free of charge, under strict medical supervision, the pharmaceutical preparations that contain nicotine which, although they do not decrease dependency, they

¹⁸⁰ Some information about the activities can be found on the Ministry of Health 2011 Report on Smoking Prevention Activities.

do have the advantage of avoiding the assumption of all the carcinogenic compounds produced by combustion.

Regarding alcohol the actions of the government have so far been very bland. The Alcohol Health Alliance has prepared a series of 30 recommendations which include inter alia the abolition of advertising as is done for tobacco and an alcohol tax rise in order to increase the price of the minimum unit of alcohol served to the public. The need to place clearly visible warnings on the bottle containing alcohol to make the damage caused to health known is also envisaged. There should be a drastic decrease in blood alcohol concentration in those who drive private or public vehicles or manoeuvre dangerous equipment as well as the use of alcohol during pregnancy. Lastly there should be an increase in the services open to alcohol-dependent patients by the NHS to provide support and detoxification treatments.

As for foods and drinks with a high energetic value first and foremost it is very important to achieve widespread information, to identify the products most at risk and to spread knowledge based on scientific evidence. Individual product labels are another important vehicle of information. There should be the requirement for companies to place on their products labels with clear and simple information on the calories per serving as well as educating the consumer to read the information regarding the quantity of calories per portion and the amount of sugar, cholesterol, saturated and unsaturated fats. This information should be accompanied by an explicit indication and risk assessment (similar to the side effects listed in the packaging of medicines). From the point of view of disincentives there could be an extension of recourse to a tax on sugar and fat, so as to encourage manufacturing industries to modify the formulation of their products. Conversely there should be support for the production and distribution of vegetable products or other healthier foods.

This series of possible interventions, presented for purely illustrative purposes, to be implemented at household, school, social and State level, should allow promotion of strong global action indispensable to achieve significant results.

Recommendations

The National Bioethics Committee, on the basis of the considerations above, puts forward the following suggestions aimed at finding effective syn-

ergy between the responsibility of individuals for their own health and the State's responsibility to protect health, which is recognised as a fundamental right of every person.

1. The NBC believes that the State should not exercise a right of control over personal decisions, unless they entail risks that directly threaten health or the life of others. Nevertheless, the State must implement its interventions to improve primary prevention which could be done through a global project that will result in:

- taking into account in the genesis of diseases the social and environmental determinants that affect health and modern forms of poverty and inequality that significantly influence levels of health in general and also the negative consequences of individual behaviours;

- promotion of the researching of scientific evidence on the causes of the risk factors for health (e.g. the link between obesity and the consumption of certain foods or certain metabolic causes); psychological research on motivation and demotivation with respect to responsible lifestyles for health, not forgetting that there is often a social component in the consumption of alcohol or in the way of eating and that lifestyles can be dictated by social customs, or indeed by veritable rituals); research on the social effectiveness of certain interventions (e.g. the relationship between the rise in prices and the decrease in consumption of a product which is harmful to health) and their social impact; research on the necessary tools and methods, proving effective and proportionate for public health;

- promoting measures to make it easier to provide people with the opportunity to lead healthy lives even according to the logic that leads back to "nudging", i.e. favouring promotion without impositions (e.g. promoting architectures and public spaces to encourage physical exercise; facilitating the opportunity to opt for healthier foods by clearly labelling products or explicitly specifying different options in restaurants, etc.);

- recalling industries to corporate social responsibility, discouraging, by way of appropriate regulations, right from the outset the production and marketing of products that are potentially harmful to health, condemning deceptive marketing strategies and advertising campaigns; in this respect it would be appropriate to take into account the need to compensate for the economic harm suffered by the NHS with the accumulation of wealth

by commercial enterprises which put into circulation products which are particularly harmful to health (such as cigarettes proven to have pathogenic effects): indeed product taxation policies affect the consumer, often without significant disincentive effects, while any possible compensation that companies would have to pay to the national service - at least based on the correlation between higher charges for the service itself and the accumulation of wealth by companies - would contribute to relieving, at least in part, the public body from this expense; rather than burdening the consumer who falls ill, the burden is placed on those who benefit from the consumption;

- promoting innovative research of products that do not damage health;
- adhering to and proposing integrated interventions on a European and global level¹⁸¹;
- implementing appropriate policies for economic and non-economic incentives and disincentives to encourage citizens and induce behaviours capable of reducing the burden of disease on society.

2. It is important on the social level to set in motion the appropriate means of information and education to enable all citizens to become aware of the connection between the right to health and the duty of social solidarity, which involves attention to the consequences of one's lifestyle. A conscious and responsible attitude on everyone's part guarantees all, including future generations. In this sense, it is desirable to plan stable, not occasional initiatives in schools; informational and educational policies aimed at society at large should be promoted and supported financially. However, as already recommended in this Opinion, the construction of a primary prevention program cannot discriminate against those who do not adhere or those who practice "bad" habits. Indeed society should address these people at risk of disease, supporting and publicising care services, to help them to recover lifestyles better suited to maintaining a good state of health.

¹⁸¹ See, the European Commission, "Health in all policies" (http://ec.europa.eu/health/health_policies/policy/index_it.htm) or "Europe 2020 - for a healthier EU" (http://ec.europa.eu/health/europe_2020_en.htm); the World Health Organization, see the program Health in All Policies (<http://www.healthpromotion2013.org/health-promotion/health-in-all-policies>).

3. Lastly, the responsibility of the media in the presentation of scientific information on health is to be recalled, so that they are aware of the impact this will have on the public. Informative interventions must pay particular attention to the most vulnerable categories. Appropriate regulations are called for to protect minors with regard to the advertising on television and the Internet of products that can damage their health.

Presidenza del Consiglio dei Ministri



PEDIATRIC BIOBANKS

11 April 2014

Presentation

The National Bioethics Committee has already made some examination of the general theme of biobanks in previous documents.

In this Opinion, the Committee deals with pediatric biobanks, characterised by the collection of biological samples from minors and aimed at scientific research.

The document, starting with the recognition of pediatric biobanks as a valuable resource for scientific research, addresses emergent bioethical issues.

It upholds the general ethical principles involved in the donation of biological samples (accreditation of biobanks, free donation, protection of privacy), addresses some specific problems with regard to the vulnerability of minors (informed consent of the parents and the child on becoming an adult, the principle of subsidiarity, risk/benefit assessment, the right to know and not to know).

The Committee emphasises that the interests and welfare of the individuals whose biological material is used for research must always prevail over the sole interests of society or science - even more so if they are minors.

To this end, the Committee reiterates the need for normative regulation regarding this field that takes into account aspects of ethical importance: adequate and detailed information (scientific interest of research, protection of privacy, time and place of research) to the parents or the legal representative for purposes of consent which is appropriate whether it be restricted or partially restricted; listening to the will of the minor, in relation to progressive states of maturity, as well as informing the minor as regards the disposal of his biological material by parents and those in charge of biobanks; limitation of the parents' right not to know in cases where the information is trustworthy and useful for the health of the minor in preventive and therapeutic terms; the guarantee of the right to know or not to know, of the minor on becoming an adult and being capable of adequately expressing will.

The Committee also considers necessary the establishing of a supervisory body for the various phases of conservation and management of biological material and the presence of an ethics committee; it recommends appropriate training for the researchers and staff of the biobank; and calls for a census of pediatric biobanks and the possibility of establishing a National Registry.

The working group was coordinated by Prof. Lorenzo d'Avack, who drafted the original text.

Professors Salvatore Amato, Bruno Dallapiccola, Carlo Casonato, Marianna Gensabella, Assuntina Morresi, Laura Palazzani and Dr. Carlo Petrini contributed to the final draft of the Opinion.

The text was discussed and unanimously approved in the plenary session by those present: Profs. Salvatore Amato, Carlo Caltagirone, Stefano Canestrari, Cinzia Caporale, Carlo Casonato, Bruno Dallapiccola, Antonio Da Re, Mario De Curtis, Riccardo Di Segni, Paola Frati, Silvio Garattini, Demetrio Neri, Andrea Nicolussi, Laura Palazzani, Rodolfo Proietti, Massimo Sargiacomo, Lucetta Scaraffia, Giancarlo Umani Ronchi, Grazia Zuffa.

Profs. Luisella Battaglia, Francesco D'Agostino, Marianna Gensabella, Assuntina Morresi, absent from the session, subsequently expressed their approval of the Opinion.

Dr. Carla Bernasconi (FNOVI), Dr. Rosaria Conte (CNR) and Dr. Carlo Petrini (ISS), present as *ex officio* members, also affirmed their support. Prof. Monica Toraldo di Francia, absent during the plenary, sent a personal remark.

The President
Prof. Francesco Paolo Casavola

Preamble

In this Opinion, faced with different meanings, for the term biobanks we mean: the operative service Units, assigned to collect, preserve, classify, manage and distribute the human biological materials (cells, tissues, DNA) of individuals or groups of healthy or sick individuals, for biomedical purposes (research, diagnosis, prevention or treatment), inside hospitals or research centres.

It is possible to draw a distinction between two types of biobanks, in connection with their different purposes: depending on whether the biological material is stored for research purposes or for clinical/ therapeutic use, that is, intended for human application. This second type is regulated by specific European legislation (Recommendations 2004/23 EC 2006/17 EC and 2006/86 EC), while for the first, nothing analogous exists yet.

The present Opinion deals with pediatric biobanks, characterised by the collection of biological samples from children and aimed at scientific research. The preservation of human gametes and embryos, which opens different ethical issues, is excluded from present deliberation.

It should be noted that the establishment of biobanks, which collect biological material from both adults and minors, stems from a complex process. At each stage of this process, those acting may be different: the individuals who take the samples, collect the data and information are different from those who manipulate the biological derivatives, label them, encode them, and make them anonymous or identifiable again. Similarly the personnel entrusted with the storage of samples is very often different from the personnel responsible for management of the information regarding samples. Yet another different body of personnel is involved in using the samples for research. It therefore seems appropriate, even more so in the case of biological material collected from minors, to ensure a clear chain of management of the different tasks by setting up a supervisory body in the figure of a guarantor/curator of the procedure responsible for both the proper storage and utilisation of biological material as well as for the management of information, handling relations with families and the minor, on becoming an adult.

This means that all the stages in the process must be regulated in a coherent and responsible manner, taking into account technological advances.

“The collection of biological material - as the National Bioethics Committee (NBC) and the *National Committee for Biosafety, Biotechnology and*

Life Sciences (NCBBLs) were able to observe - together with the clinical information connected to the individual are an indispensable tool to elucidate the molecular mechanisms and causal pathways, whether they be genetic or environmental, and translate biomedical research into improvements in care research based on biobanks will give rise to new synergies between industry and public research facilities, strengthening the competitiveness of our country within the context of health industries. In addition to the ultimate goal of prevention and treatment of complex diseases, a short-term benefit will come from the development of new and more powerful diagnostic tools¹⁸².

Despite being a valuable resource for scientific research, biobanks raise bioethical issues, since the archived material is usually associated with the donor's personal and biographical data, including age, sex, ethnicity, and clinical data, such as the place of sampling, the diagnostic procedure, treatment, the natural history of the disease, family medical history, social group membership¹⁸³.

The advances in molecular biology have changed over time the nature of biobanks. Biological samples collected have acquired considerable value, both for the researchers and industry. For the researcher this material - tissues, cells, DNA - allows identification not only of the constitutional genomic profile, but also of somatic mutations and to carry out studies that develop more effective diagnostic tools, early detection of people at risk and the development of targeted therapies. These researches have acted as a driving force in the establishment of large biobanks.

While on the one hand biobanks have a significant cognitive and scientific value, which explains their development, on the other they present critical issues for the rights of the individual in the absence of appropriate criteria for management and control. In fact, they are embedded in dynamics in which those who donate biological samples hand over material that carries their ge-

¹⁸² The National Bioethics Committee (NBC) and the National Committee for Biosafety, Biotechnology and Life Sciences (NCBBLs), *Collection of biological samples for research: informed consent*, 2009, p. 5.

¹⁸³ According to the Recommendation of the Council of Europe, n. 4/2006, a biological bank must necessarily contain in addition to the biological materials also "associated personal data, which may include or be linked to genealogical, medical and lifestyle data and which may be regularly updated".

netic identity to be used by researchers for scientific purposes, without necessarily obtaining immediate and direct benefits. Therefore the fundamental ethical problem emerges of balancing on the one hand the need for advancement of scientific research, and on the other the protection of the individuals involved (in particular the right to confidentiality of personal data). The latter are not always aware of the possible implications of certain choices and therefore cannot consciously direct the use of the collected material. Besides, whoever donates the sample may fear certain situations at different levels: on the individual level, when the biological sample or data are used for research and purposes different to those consented to by the donor and which are contrary to the donor's values, or when the sample is used for purposes other than research (e.g. insurance companies, employers, etc.); on a commercial level, when the collection of biological material involves rare material that is phenotypically well characterised which comes to have a value in economic terms, rather than for research, with the risk of its being transferred or marketed nationally or internationally; on an international level, when the use of the genetic data of a population, ethnic group, or country, dictated by an economic exchange that is already ethically hard to accept, has little or no return for the donors.

In the past, the samples were generally irreversibly anonymous¹⁸⁴ (obtained without informed consent and without a classification of the donors) and this made it impossible to trace the identity of the donor. Anonymity is in itself reassuring, since it avoids, in fact, possible violations of privacy. Today the situation has changed: full anonymity remains a possibility, but as an option of the adult individual (expressed in the informed consent form), although the relative ease with which it is possible to sequence the entire genome makes it practically difficult to ensure the anonymity of numerous biological collections. In addition, scientifically, full anonymity may represent for some research a loss in the utility of the material, given the importance for research of the associated information.

¹⁸⁴ The samples can be acquired: completely anonymously (a total lack of reference to the donor); or, in an anonymous manner, for those who carry out research, even if the origin of the sample is known by those who supervise its management (guarantor/curator) using a classification code; or always codified to protect the privacy of the individual, but those actually using it as researchers, have the possibility of opening the code and knowing the donor.

The opposite solution is the full identification of the donor. However, the ethical and normative impetus for the need to protect the privacy of the donor, has led to the intermediate model of “controlled” anonymity: the assignment of a code to each individual sample, this code is made known only to certain operators (e.g. the person responsible for the biobank or his immediate collaborators). Therefore there has been a shift from “full” to “partial” anonymity. Upon receipt of explicit donor authorisation, the individual’s identity and personal data are then made accessible to the person who has the key to the connection between the code and the data of the patient. Where it is explicitly permitted, the encryption key enables the donor to receive information regarding research results.

The present Opinion concerns the collection of human biological material obtained from residual parts of samples taken for diagnostic or therapeutic purposes in pediatric contexts and which, as already mentioned, are only intended for research¹⁸⁵. These samples also include those taken through mandatory newborn screening aimed at the diagnosis and treatment of certain genetic diseases, and carried out using a few drops of blood, when provision is made for storage of residual material after the performing of the tests required by current legislation¹⁸⁶.

¹⁸⁵ The NBC and NCBBS, through the drawing up of the documents, *Biobanks and research on human biological material*, 2006, *Guidelines for the establishment and accreditation of biobanks*, 2006, and *Collection of biological samples for research purposes: informed consent*, 2009, have already stressed the importance of biobanks for research purposes as regards the scientific aspect. These documents, have treated many ethical, scientific and legislative issues related to biobanks in general, however, there has not yet been an in-depth treatment of the issue of pediatric biobanks. Take the closely related ethical problems raised in the Opinions of the NBC and NCBBS, *Long-term storage of residual dot blot spots from neonatal screening*, 2010. As regards the ethical issues that arise from testing and genetic data, one should refer to the NBC Opinion, *Bioethical guidelines for genetic testing*, 1999 and NBC-NCBBS, *Genetic susceptibility testing and personalized medicine* 2010.

¹⁸⁶ Pursuant to Art.6, paragraph 2 of Law 104/1992 and subsequent implementing decree DPCM 9/07/1999. The Tuscany region has expanded mandatory newborn screening to more than 40 rare metabolic diseases and certain immunodeficiencies such as ADA deficiency. While other regions have their own programs: e.g. Umbria with a memorandum of understanding adopted the program of Tuscany in 2010. Significant is the case of Emilia Romagna, where the resolution of February 1, 2010, no.107 included 24 diseases and has sparked a dispute which from the TAR (Lazio regional administrative court) has reached the ECHR. The disparity between regions is to be overcome by virtue of paragraph 229 of the stability law (2013 n. 147), which provides for extended screening everywhere and which in order to encourage maximum uniformity throughout the country has established a Coordination Centre for newborn screening within the National Agency for regional healthcare services (Age.n.a.s.) a Coordination Centre for newborn screening.

There is a lack of attention, in general and particularly in our country, regarding the treatment of the samples taken from minors¹⁸⁷. The few regulatory documents¹⁸⁸ lack specific references to minors. And the limited references available are insufficient, as they relate to situations related to a possible diagnostic and therapeutic benefit for the minor, while in the case of pediatric biobanks, as will be pointed out below, the sample is donated and used for research with the predominant philanthropic purposes, regardless of any possible or certain clinical benefit for the donor.

1. Ethical principles for pediatric biobanks

In other documents relating to biobanks in general the NBC and NCB-BLS committees have already had occasion to point out certain ethical principles that are fully endorsed for the concession of biological pediatric material and more specifically:

- biobanks must apply for and obtain certification through a transparent procedure approved by a body recognised by the government¹⁸⁹;
- the biological samples belong to the donor and are given under “the general formula of ‘concession for use’ confirming in any case the principle of gratuity and the prohibition of personal discrimination”¹⁹⁰;

¹⁸⁷ For a pilot study that outlines a survey of pediatric biobanks at European and Italian level see E. Salvaterra et al., *Pediatric Biobanking: A Pilot Qualitative Survey of Practices, Rules, and Researcher Opinions in Ten European Countries*, “Biopreservation and Biobanking”, 2012, 10, 1, 29 ff. The datum that emerges is the heterogeneity of practices and the need for homogeneous bioethical and biollegal recommendations.

¹⁸⁸ Regulation of the management of clinical biobanks in the conservation of stem cells from umbilical cord blood for autologous use, conservation authorised only within public facilities devoted to this (Ministerial Decree of 18 November 2009). The procedures for the establishment of bodies responsible for certification of clinical biobanks such as centers for biological resources (CRB) is regulated by the Decree of the Ministry of Economic Development (2006). Law 30.06.2009, n. 85 specifically enacted to establish and regulate a national database of DNA for forensic purposes. To be considered is the *Authorization of the guarantor of privacy on the processing of genetic data* (12 December 2013) and the *General authorization of the guarantor of privacy on the processing of personal data carried out for purposes of scientific research* (12 December 2013) that are also relevant to biobank regulations concerning the use of tissue and archiving of patient data. Even the European regulations cited above, concerning the clinical use of biological samples, never make explicit reference to children, speaking only in general of “people who give authorization on behalf of the donors” (2004/23/EC, art. 2 paragraph 13), but as for consent they refer to national legislation without distinctions for the age of the donor.

¹⁸⁹ NCBLS, *Guidelines*, cit., 10 et seq.

¹⁹⁰ NBC-NCBLS, *Considerations*, cit., 25 et seq.

- the concession¹⁹¹ of the biological samples of minors by their parents/legal representative collected in biobanks for research purposes are of great benefit to science and health, however these goals are not to prevail over the rights and interests of individuals involved in the research¹⁹².

More specifically it must now be considered that minors are a particularly vulnerable category, and therefore appropriate protective measures are required also in the specific case of the concession of biological samples for research. In addition, research involving pediatric biobanks raises different ethical issues to the research using biobanks that collect material provided by adults. In fact, children have limited capability to understand the meaning and implications of the research and to express informed consent, these capabilities are only acquired gradually. On the other hand, although the collection of biological samples is generally associated with the pharmacological experimentation, as previously mentioned, it is neither possible nor appropriate, given their specificity, to apply to pediatric biobanks the ethical principles and legal rules of biomedical research on minors¹⁹³.

It should also be noted that the threshold of concern in safeguarding the rights of minors can be placed at variable levels, since the use of biological material is highly heterogeneous.

Therefore, some of the most problematic aspects of pediatric biobanks will be taken into consideration in this document: consent, subsidiarity, the risks/benefits, and return of results¹⁹⁴.

¹⁹¹ In the context of this document, despite noting the correctness of the expression ‘concession for use’, the word ‘donation’ is mainly preferred as it is a term used internationally even when referring to minors and moreover it expresses the gratuitous dimension of the act.

¹⁹² Principle reiterated in every opinion in strict accordance with the conventions, EU and international regulations and recommendations (e.g. In Articles 8 and 9 of the General Principles of the *Declaration of Helsinki*, 2013 in the Preamble to the *Rec*, 2006, 4 of the Council of Europe on *research on biological materials of human origin*, in the Introduction of the *International Declaration on Human Genetic Data* UNESCO, 2003; Art. 2 of the *Oviedo Convention*, 1997).

¹⁹³ To refer to our regulations: Art. 4 of legislative decree 211/2003.

¹⁹⁴ We will omit discussion of certain customary topics in the context of biobanks such as the status of the detached parts of the human body, the storage conditions of biological materials, the researcher / biobank ratio, biobank certification, the commercialisation of results, etc.

1.1. The consent of parents and the minor/adult

Before any collection of biological material is carried out, it is necessary and of primary importance to have the free and clear consent of the actual donor. And the requirement of biobanks to make use of the consent of participants stems from the fundamental principles relating to biomedical ethics: all documents, agreements and regional and international regulations on the subject emphasise this requirement and its importance.

However, in the case of pediatric biobanks, this prerequisite for various and not marginal aspects raises issues with respect to biobanks collecting material obtained from adult donors given that: a) the material collected does not actually belong to the person granting it, but to another individual, in this case a minor, who comes under the vulnerable individual category; b) minors, until they acquire the capacity of discernment, are not able to give informed consent concerning the destiny and future of their biological material.

In the juridical context it is believed that the will and wishes of minors, in view of their best interests, are manifested by the parents or legal representative. The consent of the parents or legal representative must therefore always be declared at the time of the concession of the biological material of the minor/child to the biobank. This should, however, be subject to the information to be given to the minor at the time of the concession of the samples, taking into account the degree of maturity reached by the minor and the ability to understand the information sheet, given that any possible refusal of the minor shall prevail over the consent of the parent/legal representative¹⁹⁵.

It should also be considered that doctrine and legal systems provide for different modalities of consent to the concession of biological samples: “limited consent” to the use of the sample, only for immediate, specified research, which prohibits use in other studies not provided for at the time of signing; “partially restricted consent”, which authorises the use of samples not only

¹⁹⁵ As indicated in the Additional Protocol to the Oviedo Convention on scientific research where it is written that, among the conditions to be met in order to conduct research on people who did not have the ability to give informed consent, there is the one regarding non-objection on the part of the subject concerned.

for specific current research, but also for future research that is directly related to the initial one; “multi-option consent”, which allows to make different choices, all explained to the donor by the biobank; “broad consent”, which allows the use of samples for current and future research of all kinds.

In the first three cases, it is expected that donors may have constant control of their own samples and may withdraw given consent at any time, resulting in the destruction of biological samples and related data. Participants must be informed about the content of each individual research project in which the biological samples are used, so as to enable them to evaluate on the basis of knowledge of the project if it is compatible with their moral vision and the goals expected from the research.

In the case of “broad consent”, the donor relies on a general information sheet and it is clear that in this way a relationship of trust is established with the biobank, based on the prevailing principle of social solidarity, a reason which in itself justifies the research. An agreement of this type is often called for by researchers in order to have greater freedom in the use of materials and not negatively affect subsequent research on the samples provided.

In view of these various options, the NBC/NCBBLs recognised as an appropriate model of informed consent “partially restricted consent”¹⁹⁶.

In the case of pediatric biobanks, with consent not coming directly from the participant, and given that the concession of biological samples of the minor may not be neutral in its effects, the NBC reiterates, as in another document of the same Committee¹⁹⁷, that the samples should not be rendered anonymous irreversibly and the authorisation of the parents or legal representative should not be “broad”, but rather given for a specific research or one directly related to it (“partially restricted consent”), after receiving detailed and full information, so that the giver can assess the aims, duration, place and manner of implementing the scientific project in which the sample is used. Parents, therefore, retain, “control” over the use that is made of the biological material of their child, so as to be able to request an informative

¹⁹⁶ NBC-NCBBLs, *Collection of biological samples for research purposes: informed consent*, 2009, p. 14.

¹⁹⁷ NBC-NCBBLs, *Considerations*, cit., p. 25.

report and its destruction following the withdrawal of consent (destruction of both the biological samples and the biographical/associated clinical data).

In addition, parents should be reassured about the management plan and the manner in which the biobank ensures the retention and the “confidentiality” of the collected data. Prohibited access of certain third parties, such as insurance companies¹⁹⁸ and employers should also be made explicit.

Although the Committee insists on the importance of defining these aspects within the context of initial consent, it is nevertheless aware of the difficulty of setting these objectives in a comprehensive way at that time. In fact, the time span of the research is generally long and it is difficult to predict at the moment of giving consent, the possible studies which, after several years could involve the material being re-utilised. This implies that for the proper management and utilisation of the material granted to a pediatric biobank the essential rule, when the minor heads towards maturity, is the loss of importance of the consent given by the parents and the start of a process aimed at listening to the actual adolescent. Those becoming legally of age must have the opportunity to immediately give their consent or, if the research has already begun, renew, modify or withdraw consent to the use of their samples and data in the biobank.

Consequently the head of the pediatric biobank (guarantor/curator) must develop procedures which enable the child on coming of age to be contacted via appropriate means, to obtain adequate information, to be given the opportunity to withdraw or access samples and data and destroying them or delete the registered information. The Committee believes that the data and results of prior research to the eventual destruction of biological samples may be used and published, while respecting anonymity.

The NBC points out that in the context of informed consent it is the responsibility of the biobank to explicitly invoke the duty of parents to inform their child regarding the donation and to maintain contact with the biobank to enable the latter to succeed in the consent.

¹⁹⁸ The NBC/NCBBLs in the Opinion *Genetic Testing and Insurance* (2008) stressed the importance of ethics, in the context of the use of genetic test results, with regard to the principle of non-discrimination, recommending that insurance companies should not ask users to undergo genetic testing, allowing however, the possibility to use the results of genetic tests that have already been carried out, with the consent of the person concerned.

Also to be considered is the fact that the samples and the information are often transferred - in the context of international and multi-centric research - to other biobanks or different research groups and can be shared with the researchers of other countries (subject to different regulations) so the cancellation of all the information is often complex, if not impossible. In view of the theories that deny the possibility of the dislocation of biological samples of minors, the Committee believes that this should be allowed on the condition that the parents are made aware of this problem at the time of the concession of the biological material, and also the minors themselves when asked for their consent.

A specific problem is the request for informed consent for the use of the biological samples of children with rare pathologies, where the need for research is particularly important. It is important in order to increase the provision of samples in the informative interview that the physicians present the parents/legal representative with the particular significance of this gesture of solidarity, which is essential for the advancement of research for the benefit of other sick children.

However, even within the regulation of pediatric biobanks, there may be exceptions to the continuation of research if there is no expressed will regarding a greater or different use of samples and data compared to the one originally proposed by the parents, or without the subsequent consent of the child. These exceptions are also provided for in the General Authorisation of the Privacy Guarantor in relation to “the processing of personal data carried out for purposes of scientific research” (2012). In the first place, should the processing of data and samples be necessary for conducting studies, with no significant impact on the individual participant, carried out with organic material collected previously for the purposes of protection of public health or for the execution of earlier research projects.

A second exception may be construed when it has not been possible to contact the minor, now adult or the parents, even though reasonable efforts have been made to do so.

In both exceptions authorisations should include the possibility of conducting research with similar goals through the processing of anonymous data or data relating to persons from whom informed consent has been or may be acquired. In addition, these exceptions are admissible unless previously stated otherwise by the actual participants.

However, in these cases, as in all biobanks, research can only be carried out on the basis of a project that has received the approval of the competent territorial ethics committee, which has assessed its scientific appropriateness and ethical acceptability.

1.2. Subsidiarity, risks and benefits

The ethical and legal principles which legitimise scientific research on groups of vulnerable individuals include those that research must be responsive to the health needs and priorities laid down by that category of persons, and that the same research cannot be carried out on non-vulnerable persons. In addition, this group should benefit from the knowledge, practices or intervention deriving from the research¹⁹⁹.

It should also be noted that there are established general ethical principles for research on incapacitated persons “with no direct benefit”:

- The research project must envisage collective utility;
- The risks and inconvenience to the persons involved should be minimal.

These rules are often cited in the literature for pediatric biobanks. Notwithstanding the already stated differences between scientific research on minors and the collection of biological materials for pediatric biobanks, there is no doubt that the two requirements by way of exception mentioned above are present in this last case treated. The scientific aims of pediatric collection presupposes collective utility and its objective is to enable a significant expansion of medical knowledge on the specific medical condition (e.g. disease) of the group to which the minor involved in the research belongs. The need for scientific research on the biological samples of minors, even if replaceable in some cases with research on the biological samples of adults, in accordance with the principle of subsidiarity justifies the use of the samples collected in pediatric biobanks.

In the present case, therefore, the possibility of a minor to obtain some future medical benefit, not in immediate and specific relation to the time of concession, should not be totally ruled out.

¹⁹⁹ *Declaration of Helsinki*, Art. 19-20, 2013.

It has been noted, in addition, that minors “benefit” from being generous and supportive to the community, through the choice made by their parents to donate their samples. In this sense, the best interests of the minor would at least partially be represented by the contribution that he provides to the community.

Accordingly, even if a minor does not directly and immediately benefit from the research, it appears justified from the point of view of personal benefit, since it could in future determine some benefit in terms of health to the minor-donor, but also from the ethical perspective, as it is necessary for society.

The other aspect, that of “minimal risk” has been discussed in the context of research, especially on incapacitated persons, and consequently in pediatric biobanks. Primarily, the difference between the two types which jeopardise varying interests should once again be emphasised: health in the first case, in the second the right to protection of personal data. Therefore, it is of primary importance in the context of biobanks to have regulations that guarantee specific protection of privacy, particularly when samples are shared with other researchers not connected to the biobank, which has acquired the sample. Therefore, the preference given to “partial anonymity” through codes both for the samples and the data from a minor is justified for the obvious reinforcement of privacy, unless the use of the biological material or associated data in the “not anonymised” form is in line with the best interests of the actual minor. Once the risk of a breach of confidentiality in its percentage of occurrence is reduced, the limitations in terms of risk to the use of pediatric biological samples tend to diminish. However, it should not be overlooked that if, in general, in the case of biological samples taken from adults the effects on the donor are not significantly burdensome, for children the moment of collection of their samples may have a greater psycho/physical impact resulting in a burden that is not always tolerated and justified in the face of the absence of direct benefits. A potential burden for example may relate to the need for any additional measures to the taking of the sample (taking additional blood or tissue samples etc.). Moreover burdens of another kind may arise from the knowledge subsequently acquired by the minor, on becoming an adult, regarding the type and seriousness of the disease suffered from in the past or some genetic information concerning him which could have a psychological impact on his life.

However, given the general difficulty in the field of research on the incapacitated and minors, to define what risks and inconveniences are minimal and therefore tolerable for the benefit of scientific and social interests, the NBC, instead of referring to fixed and predefined standards, endorses evaluation of the situation, taking into account the context of the study and the particularity of collections by the appropriate ethics committee.

1.3. The Right to “know” and the right “not to know” of parents and the legal representative

Normally biobanks do not communicate to those who have conceded samples the data obtained from the research carried out utilising their samples, except at the express request of the person concerned, as expressed at the time of consent. In fact, in a research context, the results obtained on a sample must usually be validated on other samples. Moreover basic research operates under different conditions compared to traditional laboratory research. It would not therefore be appropriate for the patient’s physician to use these results as part of subsequent care, until the study results are not confirmed by subsequent investigation capable of verifying their clinical relevance. Nevertheless, some data obtained from the study of samples can provide useful information on the subject’s health (prevention, diagnosis, treatment) or identify genotypic characteristics that may be passed on in the family (significant in the context of procreative choices).

It is now known that as part of the right to self-determination established in our society, both on an ethical and juridical level, with reference to choices in the context of genetic information, there is also the right to remain in “ignorance about one’s future”, i.e. the “right not to know.” Donation of a biological sample that is immediately completely anonymised is characterised by not asking or expecting anything in return, not wanting to know the next phases and results of the research. This is a possibility as part of the informed consent of adults.

With regard to pediatric biobanks, the Committee believes that the informed consent of the parents/legal representative to the donation of biological samples should explicitly provide for the information sheet to be given, if the research provides sufficiently substantiated, reliable and useful information for the health of the minor on the preventive, diagnostic, therapeutic level or in terms of reproductive health. In this case - in the face of actual

and potential benefits - there is the researcher's duty to inform and a right/duty to know on behalf of the parents/legal representative in the interests of the minor²⁰⁰, even if this entails a burden in terms of costs and on an organisational level for biobanks, as well as a psychological burden for the parents themselves. The parents /legal representative should therefore not be granted the opportunity to express their dissent to being informed and to assert their "right not to know." After concession of the biological material of the child in coded form and this can be traced to the person concerned and how potentially these samples are a possible source of various types of information (medical, biological, genetic, etc...) it is in the interests of parents²⁰¹ and of the minor to obtain the informative report concerning the health of the minor, given the possibility to take preventive and curative action in his favor²⁰². Those responsible for the biobank should do everything possible to contact the parents or the legal representative of the minor and give them the informative report.

The Committee also considers it necessary that the parents or the legal representative must be informed, even in the case of possible data, not explicitly searched for (so called 'incidental findings', or 'unexpected results'), which highlight genetic diseases with either certain or high probability of late-onset with no current cure (e.g. Huntington's disease). These situations, whilst being infrequent, given the consequential ethical issues, should always be clearly defined as possible and brought to the attention of the parent/legal representative within the context of consent to the donation of biological samples for genetic research.

It will, however, be the duty of physicians to select the relevance of the information and the duty of parents to use this medical data in accordance with the appropriate needs of the minor and to assess when and how to transmit this knowledge to their child.

²⁰⁰ This is in accordance with the "duty of care principle" of the Additional Protocol to the *Convention of Oviedo* research (Article 27) and to the Explanatory Report (paragraph 134).

²⁰¹ Moreover, the genetic information could be relevant to the parents themselves, for their health and their reproductive choices.

²⁰² Even the 2006 *Recommendation 4* of the Council of Europe underlines the risk that may result from the maintenance of the rule of "non-identifiable" or "irreversibly anonymised" material in genetic research.

It will be the latter when an adult, as part of his consent to research to make use of the right to be informed or the right not to know.

In any case, in the context of a return of information, the Committee recommends the help and support of experts as part of an appropriate advice service, given the complexity of the information²⁰³. The information must be transmitted to parents in an understandable form; the understanding of the communicated results must be verified and, if necessary, psychological support must be guaranteed.

Recommendations

The collections of biological samples present in the pediatric biobanks, are of extraordinary interest for research in biomedicine, in particular biomolecular engineering and in translational research. However, the need to correlate tissue samples and personal data raises the issue of confidentiality and protection of personal privacy. The Committee underlines that the interests and welfare of the individuals whose biological materials are used for research must always prevail over the sole interest of society or science, and this applies all the more if they are minors.

The Committee reiterates the need for legislative regulation on this subject, able to provide guidelines in conformity with the directions that come from European and international papers.

As regards the correct procedures for the acquisition of biological samples from infants and minors, the NBC, while hoping for their donation, believes that the consent of the parents/legal representative cannot be broad and irreversible, but fairly restricted or partially limited, filed in written form at the time of taking the biological sample for diagnostic purposes, as a result of detailed information concerning:

- the exclusion of direct commercial purposes for research and the guarantee that research is carried out in accredited facilities;
- the objectives of the biological sample and the scientific interest in participation in the study;
- the nature of biological materials and the data collected;

²⁰³ For genetic counseling it is important to refer to the interaction between genes and environmental factors and the possibility of false-positive or false-negative results.

- the intended use of samples and data;
- the measures taken to protect the privacy of the minor and possibly his family and the socio-cultural environment in which he / they belong;
- the times and places of research (the possible transfer of samples to the facilities/research groups different from the one intended for the sample);
- the financiers and the identity of the manager or responsible control body of the biobank and how to contact him/them.

The minor, in relation to his progressive maturity, should be listened to and his expressed will must be taken into account. Moreover, if research was begun in an earlier period, he must have a way of knowing that he was enrolled and know about the destiny of his biological sample and the possible results emerging from its use so as to be able to confirm or modify or withdraw consent and possibly seek its destruction or the anonymisation of the sample and connected data without being traceable.

At the time of collection of biological samples the operators and/or persons responsible for the biobank are to encourage the parents to inform their children once they are adults, regarding the donation of their biological samples.

The biobank shall make a reasonable organisational effort to recontact minors once they are adults: this operation can also be facilitated by the use of information technologies. This instrument, in accordance with the privacy policy, allows the maintaining of contact between donors and biobanks.

The Committee recommends that biobanks should implement resources and the organisational structure to communicate validated and useful results - with reference to present and future health and quality of life - to the parents and the minor now an adult.

The parents' right not to know is limited in those cases where the information is sufficiently founded, reliable and useful to the health of the minor in preventive and therapeutic terms. Furthermore, the Committee also considers it necessary for parents or the legal representative to also be informed in the case of possible data not explicitly searched for, so called 'incidental findings' which reveal genetic diseases with either certain or high probability of late-onset with no current cure.

The right to know or not to know of the minor, now adult and able to adequately express his will, should be the object of choices within the framework of informed consent.

There must be a supervisory body for the various phases of conservation and management of the biological material and associated information. The model can be represented by a guarantor/curator with the responsibility for both the proper conservation and use of biological material, as well as information management, handling relations with families and the minor when an adult.

It is also necessary for pediatric biobanks to be connected to an ethics committee, capable of assessing the scientificity and ethicality of the research, ensuring observance of the consent and wishes of the minor during his development.

Also recommended is the adequate training of the researchers and staff of the biobank as regards emerging bioethical issues attention to ethical issues would allow for greater protection of minors, helping to build a relationship of trust between donors and researchers.

Despite awareness of the difficulties encountered by repeated exhortations to carry out a census of biological banks and collections of samples present in Italy, the NBC, reiterates the opportunity to establish a National Registry of pediatric biobanks.

A Personal remark signed by Prof. Monica Toraldo di Francia

Whilst agreeing with the general approach and most of the content of the document on pediatric biobanks, I abstained from voting because I dissent on one point, while, however, recognising its great delicacy and complexity: the one on the right/duty of parents to be informed in the event the “research provides sufficiently substantiated, reliable and useful information for the health of the minor in preventive, diagnostic, therapeutic terms or for reproductive health”, and even in the event “of possible data not explicitly searched for, (so called ‘incidental findings’) which reveal genetic diseases with either certain or high probability of late-onset with no current cure (e.g. Huntington’s disease)”.

I will attempt to explain the reasons for my dissent below:

1) While I have no doubts about the licitness of the limitation of the ‘right not to know’ of parents, in those cases where there is a real possibility of immediately effective preventive and curative action, I am not so convinced when the data relates to curable diseases of late onset, for which there are no preventive measures of proven benefit. In this eventuality early

knowledge of the predictive data would not have clinical utility, while, instead, it would create such anxiety and concern likely to adversely affect family relationships; I also think that, in this type of situation, one should also consider the fact that at stake are the strong vested interests of the pharmaceutical companies for the minor to precociously begin some kind of drug treatment with the consequent risk of unnecessary preventive ‘medicalisation’. Possibly there could be other options, to be included in the information sheet and in the consent forms (which should however be explained, face to face): e.g. asking if one wants to be informed about conditions that may affect decisions about procreation and, with regard to the minor, the possibility of contacting and informing the family paediatrician;

2) Another and even more delicate issue is the one that concerns the so-called ‘incidental findings’ (IF) highlighting genetic diseases with either certain or high probability of late-onset with no current cure. The bioethical discussion on the categories of IF regarding minors that are always best notified is still ongoing and there is contrast regarding the guidelines on the proper balance between the safeguarding of autonomy and the interests of the minor and the rights-needs of parents to receive (or not receive) information that may be important for future offspring.

While being aware of the good reasons of those who consider it a duty to inform the parents even in the case of data on genetic diseases that are incurable in late-onset, however I believe that the expected benefits from this notification are not sufficient to offset the risk of a potential impairment in the psychological development of the minor and violation of his ‘autonomy’. The (obligatory) knowledge of such information would inevitably cause in parents anxiety and psychological stress which have repercussions, even more than in the previous case, on the relationship with the children, a relationship which would be disturbed by the lack of transparency caused by the presence of a dramatic ‘secret’. However, should the parents decide to inform the minor, the child would be precluded the possibility of thinking of ‘an open future’, we should ask ourselves how, self-perception and being perceived by those closest to us, as a person destined to have an unfortunate fate and an early death (compared to the life expectancy of the average person), may reflect on and influence the development of their sense of self, self-esteem and identity, exercising coercion in advance on life choices. In this case the person in question would be not only denied the right to choose

for themselves whether or not to know the genetic information about their own health, but may also be more exposed to discrimination and/or social stigma. Moreover, even assuming that the secret may not be revealed and that the person concerned, when of age, may be put in a position to decide autonomously, there would still be additional reasons to question the wisdom of imposing the ‘obligation to know’; these additional reasons concern more specifically, the possibility of stipulating insurance, health and/or life policies. Insurance companies in order to adjust premiums based on ‘objective’ risk, have been pressing for a long time also to have access to genetic data of a predictive nature which their potential customers are aware of and they justify their request by referring to the cardinal principle of the insurance contract: that of information symmetry between the insurer and the person insured. If, as has already happened in other European countries, even Italy gave way to the demands of the insurance companies, the families concerned who want to take out a policy for themselves and /or the minor would find a heavy premium surcharge applied or even a refusal to provide coverage.

For the reasons set out above, I consider it to be more appropriate to allow parents the option of being informed or not being informed about IF which identify the presence of genetic alterations correlated with an increased risk of diseases for which no cure or preventive measures exist and/or the identifying factors which could affect reproductive choices.

Presidenza del Consiglio dei Ministri



**DEMENTIA AND ALZHEIMER'S DISEASE:
ETHICAL CONSIDERATIONS**

20 June 2014

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 levels), with regard to the economic costs for society and healthcare policies at national and international levels.

The Opinion examines the bioethical aspects of particular importance: personal identity and consciousness, the communication of the diagnosis (at pre-symptomatic and symptomatic levels), 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 statements about medical 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 (President Federazione Alzheimer Italia, with Dr. Mario Possenti, her assistant), Prof. Roberto Bernabei (Director of the Department of Geriatrics, Neuroscience and Orthopedics, University Hospital "Agostino Gemelli" in Rome), Prof. Franco Cuccurullo (President 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
Prof. 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 de-

mentia 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 costs²⁰⁴ [Hurd M.D et al,

²⁰⁴ 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.

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 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 sys-

tems 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 de-

crease 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 autopsy 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 precedes 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 [Pe-

tersen 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-medial 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-amnesic 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 amnesic or non-amnesic 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 rele-

vant to increase research in early diagnosis and, the extent to 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 care²⁰⁵.

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.

²⁰⁵ See juridical part of the document.

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 dementia²⁰⁶. 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 - as far as 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 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.

²⁰⁶ 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 from 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 level²⁰⁷: 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,

²⁰⁷ 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).

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 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), ‘tele-care’ (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 the extent to 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 context of advance statements about medical treatment). 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 Europe²⁰⁸. 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 to them, it must be recalled 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 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.

²⁰⁸ Council of Europe: Recommendation 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; Recommendation Rec 10 (2004) relative à la protection des droits de l'homme et de la dignité des personnes atteintes de troubles mentaux; Recommendation 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 mental 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.

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.)²⁰⁹, by “interdiction” and “incapacitation” (art. 414 and seq. c.c.).

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 insti-

²⁰⁹ It is important to remember that also a member of the family indicated by the patient or a trusted external person can be appointed as support administrator, subject to a careful evaluation by the supervising judge.

tutes. 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 IT (Involuntary Treatment).

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 IT the legislator, through the intervention of the judge²¹⁰ 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 IT 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 IT, particularly in relation

²¹⁰ According to the Italian legislation the Involuntary Treatment 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 IT 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.

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.²¹¹. IT 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.

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.

²¹¹ Const. 39/1977; 399/1996; 218/1994.

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 health-care 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 statements about medical treatment

In these cases the possibility is recommended for the patient to avail of the so-called *advance statements about medical treatment* (ASMT)²¹², to be used when they can no longer choose for themselves. In these cases the ASMTs represent an instrument that strengthens informed consent in medical choices, giving a further possibility of involvement to the doctor’s pro-

²¹² 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 injuries, they were not able to express their informed consent or dissent’. Definition given in the NBC’s document, *Advance statements about medical treatment*, 18 December 2003.

fessional duties and to the legitimation of medical action, moreover giving substance to the patient's right to personal integrity.

In reality analogous *advance statements* can also be useful in giving guidelines with regard to the wishes of the person that, in view of the 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 *statements* 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 *statements*. 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 statements 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 statements have an inevitably precarious, contingent and uncertain nature. Nevertheless, outwardly their firm will to put the statements in writing has the mean-

ing 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 statements, 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’²¹³.

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 written statements 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 *statements* 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 statements, supported by a power conferred to the trustee or the legal representative²¹⁴, might survive the loss of the subject’s mental faculties.

2.7. Clinical trials with dementia patients²¹⁵

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 (...)”²¹⁶.

²¹³ NBC, *statements*, cit.

²¹⁴ 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.

²¹⁵ See the Opinion Clinical trials in adult or minor patients who are unable to give informed consent in emergency situations (2012).

²¹⁶ 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.

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’²¹⁷ and art. 15.1.iv of the ‘Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research’²¹⁸), 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 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’²¹⁹).

²¹⁷ 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/.

²¹⁸ 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>.

²¹⁹ 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.

It is to be hoped that in the next review of the legislation on clinical trials, which will become necessary following new community provisions²²⁰, 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 2014²²¹, 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’).

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.

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.

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

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 valued and taken into the utmost consideration. Should the decisions be

²²⁰ 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.

²²¹ 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.

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.

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.

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.

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.

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.

Presidenza del Consiglio dei Ministri



**BIOETHICAL CONSIDERATIONS
ON INVOLUNTARY EXCHANGE OF EMBRYOS**

11 July 2014

Presentation

The matter brought to the NBC's attention concerns the exchange of embryos that occurred at the Pertini Hospital of Rome, where the embryos of a couple, obtained through a process of homologous fertilisation, were mistakenly implanted in the uterus of another woman who, in turn, with her husband, had undergone an analogous treatment and is at the moment of writing of this document - carrying out a twin pregnancy.

Faced with this serious adverse event, which raises issues from a human, ethical and legal point of view, the Lazio Region Administrative Authority on May 6, 2014 asked the NBC to formulate an Opinion on this matter (see attached letter).

The NBC does not deal with the technical errors of the case, but it examines in general terms the emerging bioethical and biolegal aspects.

Some preliminary remarks on parenting and filiation within the context of Italy's current legal system are put forward.

There follows an articulated reflection on the arguments in favour of the parental subjects involved (gestational mother, genetic mother, genetic father, social or legal father) and although some members of the NBC for ethical and/or legal reasons consider one argumentative stance to be prevalent over another and highlight some critical aspects concerning the opposite viewpoint, they recognise the reasons and motivations of the other members.

Therefore, in this matter of involuntary exchange of embryos, the Committee deems appropriate not to express a bioethical 'preference' as to prevalence of one or the other possible parental figures concerned, being aware of the fact that whatever situation the children are raised in, the ethical dilemma remains open. Furthermore, there is a unanimous awareness of the tragic and dreadful nature of the events which are analysed herein and the human suffering they cause.

However, moving from the perspective of the interests of the future born, the weakest characters in this matter, the Committee formulates a series of recommendations: a) the right of those born to have two certain parental figures of reference; b) the need for the mentioned matters to be promptly dealt with, in such a way as to ensure that the children will have suitable family conditions appropriate for serene and balanced growth; c) the ethical hope that the compelling rationale of competing rights is set aside and that the families involved are able to access the dimension of responsi-

bility and solidarity towards the children, even with the legal guarantee of non-exclusion (e.g. visitation rights); d) the right of the couples to become aware of the error and the children's right to know their origins (mode of conception and gestation), through appropriate counselling and support; e) the increase in safety procedures through specific protocols, by means of effective norms in order to avoid errors.

The document was drawn up by Lorenzo d'Avack, who coordinated the working group along with Assuntina Morresi and Laura Palazzani. The document was discussed in plenary session and approved by those present at the meeting: Profs. Amato, Battaglia, Canestrari, Caporale, Da Re, d'Avack, De Curtis, Di Segni, Garattini, Gensabella, Morresi, Palazzani, Proietti, Toraldo di Francia, Umani Ronchi, Zuffa.

The members not entitled to vote: Dr. Bernasconi, Conte, Petrini also gave their approval.

Profs. Caltagirone, Casonato, Dallapiccola, Frati, Neri, Nicolussi, Scaraffia not present at the discussion also expressed their support.

Prof. D'Agostino voted against, and submitted a personal remark. A further personal remark of dissent was written by Prof. Flamigni. Prof. Gensabella, following approval of the document, also sent a personal note.

The President
Prof. Francesco Paolo Casavola

Response

1. Introductory note

The matter brought to the NBC's attention concerns the exchange of embryos that occurred at the Pertini Hospital of Rome, where the embryos of a couple, obtained through a process of homologous fertilisation, were mistakenly implanted in the uterus of another woman who, in turn, with her husband, had undergone an analogous treatment and is at the moment of writing of this document - carrying out a twin pregnancy.

Faced with this serious adverse event, which raises issues from a human, ethical and legal point of view, the Lazio Region Administrative Authority on May 6, 2014 asked the NBC to formulate an Opinion on this matter (see attached letter).

These adverse events are in principle always possible within the techniques of in vitro fertilisation whether homologous or heterologous. Awareness of the possibility of error, far from serving as a justification, should alert to the highest sense of responsibility of the medical personnel and other health professionals involved in these techniques in compliance with the security procedures provided by law.

The issues raised by these errors as regards filiation are particularly complex for ethical and juridical evaluation as they differ from case to case, depending on the defined situation. This complexity is made increasingly evident by the emergence, due to new technologies, of 'new paradigms' even with reference to the identification of filiation/parenting.

It is not the task of the NBC to deal with the specific case as regards its technical errors, rather to examine in general terms the bioethical profiles that emerge from these certainly uncommon events, which however, have also occurred in recent years in other countries.

At this point, several possibilities can be distinguished: be it that the exchange of embryos involves more than two couples or only two; be it that in all the cases a pregnancy was developed or that in some cases the embryos exchanged did not give rise to pregnancies. In the case, in fact, of an error leading to a pregnancy in both the women involved, the two couples would be in a symmetrical condition with different ethical and psychological issues.

For each situation there should then be differentiation for the case in which the discovery of the error occurs before birth and the one in which it

occurs after birth. The moment in which the error emerges, in fact, plays a fundamental role in these matters: this moment could take place at a later period, when the newborn has already been placed within a family context with consolidated emotional relationships with the result that any other parental figure would seem foreign to him.

In the face of such a wide record of cases, the NBC has decided to deal only with the bioethical profiles of the case which actually occurred of the exchange of embryos involving two couples, where the error was discovered before birth and in which only one of the two women has become pregnant (following the transfer of embryos of the other couple). A situation in which there is at the same time the presence of a gestational mother and a genetic mother and their respective husbands or partners, all keen to become parents and take care of those born.

2. Some preliminary observations

With regard to parenting - in the face of errors with an exchange of embryos - it raises the ethical and juridical problem of how to relate to the splitting of motherhood (between genetic mother and gestational mother) and the related division of fatherhood (between genetic father and the social or legal father, husband or gestational mother's partner).

In general, the legal framework in our country has been based on the assumption that the natural mother is at the same time the genetic and gestational mother. Article. 269 of the Civil Code regulates maternity establishing that it can be proven by "showing that the person who claims to be the child is the same person as the "woman assumed to be the mother" actually gave birth to; but in the absence of proof of childbirth "proof of maternity can be given by any means".

Even the regulations on homologous MAP (L. 40: Rules on medically assisted procreation) have been designed according to this model. With heterologous fecundation, as now permitted by the Constitutional Court (judgment 162/2014), there may come to be two maternal figures: one genetic and the other gestational, however, only one of these, the gestational mother, will be the legal mother.

The legal attribution of paternity is linked to genetic identity. However, in case of the pregnant woman, being married, declaring in the birth certificate the child as being conceived or born during the marriage, the husband

becomes the legal father (Art. 231 Civil Code). And in the presence of the status of being the child of another person (the husband of the pregnant woman) the genetic father can bring no action to disclaim or recognise the child.

Also for the paternal figure, a result of reproductive technology with donor gametes, genetic paternity may be terminated in favour of legal paternity.

From both the ethical and legal standpoint in the identification of maternity, and paternity, following heterologous MAP, there is the emphasis on the concept of voluntariness of the behaviour necessary for filiation, so as to allocate maternity and paternity to those parents, who, regardless of their biological contribution, want the child and accept to abide by the rules of professional ethics and the legal framework regulating MAP. Accordingly there is the rule that those who have given their informed consent to the procedure are the parents of those born and that disclaiming paternity and anonymity of the mother are not allowed (art. 9, paragraphs 1 and 2).

However, in the face of adverse events with an exchange of embryos in the process of homologous MAP, there is heterologous “by error” (the mother is carrying embryos genetically not hers or of her husband or partner) or a surrogate mother “by error” (genetic parents produce embryos that are implanted into the uterus of another woman who carries them through gestation) in a procedure lacking consent, which creates a situation of indeterminacy with regard to maternity and paternity. And the non-voluntariness (consent) to the heterologous fecundation or surrogate motherhood also implies that the rules mentioned above cannot be implemented.

Therefore, when we refer to the existing regulations, we must take account of the fact that its “rationale” is for a situation that does not provide for an error of this kind.

Also to be considered is:

- that in our case both couples, as a result of free and informed consent given at the time of accessing the technique, wanted to pursue a parental project, having expressed a desire to have children from their own gametes and the willingness to carry out pregnancy, and take on future obligations and duties from the very start;

- that the position of the couple from which the gametes originate is not comparable to that of male donor/female donor of gametes, who normally

proceed in the knowledge that they will have no parental rights or obligations on the newborn;

- from a legal standpoint, even with the agreement of the couples according to current legislation, it is not possible to hypothesise the spontaneous handing over of the newborn from the gestational mother to the couple with a genetic link, neither is it possible to envisage the registration of birth of the newborn as the child of a woman who does not give evidence of her having given birth to it.

3. What importance is to be attributed to the gestational mother and the genetic mother

In this case the primary concern that emerges among the ethical and legal problems is whether the right of the gestational mother or the genetic mother should prevail.

a. Arguments in favour of the gestational mother.

Between the gestational mother and her unborn child there are undeniable bonds of a biological, psychological and sensorial nature, that are determined and consolidated during pregnancy. The gestation period confers therefore, to maternity a specific existential value, that is both biological and cultural which goes far beyond the mere provision of the uterus. These elements of “early attachment” distinguish motherhood from fatherhood, conferring it with all those dimensions not only biological and psychological but also social and symbolic that common language expresses when it speaks of the mother who by giving birth “brings into the world” a daughter or son (registering on the unborn child, day by day, a unique and personal “biography” beyond genetics and even beyond the influence also of regulation of genes). Therefore, even in the present case of the mother who is carrying the embryo of another woman, it is believed that the expectant mother acquires the status of mother in relation to the child.

Even from a psychological viewpoint, it is stressed that the pregnant woman, in the event that, against her will, she is not regarded as being the mother of the baby, she would face two difficulties: on the one hand that of carrying out the pregnancy in the awareness of a subsequent painful separation from the child at birth and on the other of an enforced detachment, from the very beginning of pregnancy, a problematic process the mental and

physical consequences of which are not known in advance. For this woman childbirth is simply an “end” and not a “beginning”. This could be a motivation (related to ‘serious harm to physical and mental health’) to induce the woman to abortion.

In addition, a recognised right of the genetic parents on the embryo could be interpreted as a legitimate interest in the good outcome of the pregnancy and with a consequent interference in the autonomy of a pregnant woman, to her private life and the exclusive right that is recognised to her by law to take all the decisions relating to pregnancy.

As part of this contrast between the gestational mother and genetic mother causality also comes into play: whoever brings the baby to birth has directly caused the existence of this child and for the parents to be the cause of the child’s existence is not a circumstance that can be easily overlooked.

For those who maintain these claims this makes it difficult, if not impossible, to think from the ethical and legal point of view that the child - after birth - can be taken from the gestational mother in an authoritative way, “by judgment”.

b. Arguments in favour of the genetic mother.

In the present case a first argument in favour of genetic parenting is given by the fact that the gametes have not been “donated” for procreation by others but they have been collected (as is well known, in a way that is burdensome to the health of the woman) with the precise intention (informed and consensual) to achieve through technology the desire to have their “own” biological children.

In this sense, even from the point of view of causality, mentioned above, the couple have played a vital role by allocating their gametes to procreation: in total analogy to what has been said for those who bring the baby to birth, those who have provided their gametes have directly determined its existence, as without those embryos the pregnancy would not have developed.

Neither can the trauma faced by the genetic mother be ignored: It can no more be ignored even the trauma faced by the genetic mother: not having received the implantation of her own embryos because of an “adverse event”, the knowledge of having one’s own genetic children, without being able to live out the gestation period, build an emotional and social bond despite being aware of their identity, and conversely to see them grow up in another family.

In general, especially in the context of the debate on surrogate motherhood, in support of the genetic mother is a widespread thesis that the link between maternity and childbirth is, by virtue of assisted reproduction techniques better divisible and that, in the hypothesis of gestational mother, the figure of the genetic mother can take on - according to some - the contours of a “female fatherhood”, not considering pregnancy - despite its importance - the decisive factor for the construction of the parental bond. As in the case of paternity, the absence of pregnancy does not entail a decrease in the emotional intensity towards the newborn.

After failing identification with conception (with one’s own oocyte), gestation and parturition, it follows that especially from the medical point of view, the mother should be considered to be the genetic mother, since she transmits, at the moment of the fusion of gametes her own genetic heritage. This circumstance is increasingly significant even in medical terms. It is possible then to wonder whether pregnancy with one’s own oocytes cannot be lived out in an emotionally intense manner even by the genetic mother.

Should the gestational mother continue to be present after the birth of the child for its initial care needs, in order to protect the primary interests of the child, the bond of gestation may be gradually loosened and replaced by other acts of traditional care by the genetic parents: feeding, protecting and educating the child.

4. What importance is to be attributed to the genetic father and the social or legal father

The Committee also notes that the discussion on the attribution of maternity should not erase the issue of paternity. In the cases discussed there is a certain genetic father and a possible legal or social father as he is the husband or partner of the gestational mother.

The error causes, therefore, also a splitting of genetic fatherhood from legal fatherhood which, remaining in the context of our legal system can hardly be remedied by ensuring the interests of all the parties involved.

As previously mentioned, in the case of a pregnant woman who is not married, paternity under the laws in force should be attributed to the genetic father, even though this would mean that the newborn lives in two families, in a manner determined by the court in line with so-called shared custody.

It must be said that in this situation the child does not lose contact with the genetic mother, if she is married or cohabiting with the genetic father.

This is a hypothesis that can cause psychological and educational difficulties as between the genetic father and the gestational mother there would be no link of affection not even initially (unlike what can occur in separated or divorced families). And in this particular case - according to some - the definition of the parental couple would be completely defined by the child or even by the error that led to conception of the child. This would cause a paradoxical overturning of perspective: neither the family nor the couple would be strictly at the origin of the birth but the error of the exchange would determine in one way or another, the future of both the couples.

Conversely, assuming that the gestational mother is joined in marriage, according to current legislation legal paternity should be given to the husband and effectively deprive the genetic father of responsible parenting. Should it be added to this specific case that the newborn were to be denied the right to knowledge of genetic paternity this could cause suffering. This situation could result in a successive application for the denial of paternity as accorded by law.

On the other hand it should be noted that according to this hypothesis value would be given to the presence of the husband of the gestational mother, his accepting and wanting to be a father and to his being emotionally attached to the gestational mother, his sharing the parental project, and after discovery of the error, his shared choice to continue the pregnancy.

In addition, the opposite hypothesis of not privileging legal paternity, could lead the gestational mother to terminate the pregnancy, so strong and extensive would the difficulties be of raising the newborn in keeping with the intent of the genetic father, also recognised as legal father and the possible tensions with her husband to whom no authority would be granted, for any reason over the child born to his wife.

Unfortunately, it must be recalled that we are in the context of a situation of “error” which must be dealt with, with the awareness that it is not always possible to completely “repair” damage.

5. Reasoning in the interests of those born

The ethical problematicity arising from the complexity of reconciling conflicting requirements, on the one hand the need to guarantee certain

parental reference points to the unborn as well as a family, while on the other hand assuring - as far as possible - the interests of those who have resorted to MAP, with the legitimate desire to have children.

All the arguments examined in favour of the gestational or the genetic mother, or the genetic father and the social/legal father appear to be reasonable under the ethical aspect. It should also be considered that the arguments in favour of maternity and paternity delineate the possibility of several parental reference points: the gestational mother and legal or social father, genetic mother and genetic father; but also gestational mother and genetic father. Although some components of the NBC consider prevalent one line of argumentation over the other for ethical and/or legal reasons and highlight some critical issues with respect to the opposite line, everyone recognises the reasons and motivations of the others.

Therefore, the Committee deems in this matter of involuntary exchange of embryos not to express a bioethical “preference” in relation to the prevalence of one or the other possible parental figures in the awareness that whatever situation the children grow up in, the ethical dilemma remains open. In addition there is unanimous awareness of the dramatic and tragic nature of the events that are analysed here and the human suffering that they activate.

The plurality of bioethical positions on maternity and paternity are a further reason that spurs the Committee to move from another perspective: that of the interests of those to be born, the weakest protagonists in this affair.

Parents, procreators, donors are the holders of relevant ethical and legal interests, but their protection is subordinated in relation to the realisation of the interests of the newborn. The pre-eminence of the interest of the minor is one of the general principles of national and international regulations in the context of filiation. Under this general clause it follows that the rights of the child are placed in a prominent position with respect to the interests and rights accorded to parents. Normative and jurisprudential references on the subject indicate a set of inviolable and non-negotiable guarantees of the child to be connected within the context of the rights relating to personality.

Should the cases in point arouse conflict between the couple, these will be resolved in fact by the judge based on the regulations in force, although the solution of the judging body will be made more difficult, consid-

ered that the prenatal life of the children and their births are the result of particular conditions, placed within the context of an error.

The Committee hopes that the legislator will provide criteria that can regulate this kind of situation involving maternal and paternal parenting, in the face of legislation that is no longer adequate to resolve emerging issues in the field of development and the applications of new reproductive technologies.

The Committee believes, however, to be able to make some recommendations.

a) It is a primary need for minors to be entitled to have two parental figures as certain reference points, with full ownership of legal responsibilities and in a position to exercise the right to choose with awareness and authority what they believe to be best for their children.

b) The events caused by exchange of embryos once the error is known, must be addressed promptly, in time to allow the children to have appropriate family circumstances suitable for serene and balanced growth, avoiding the traumas of separation or being placed into contexts perceived as foreign.

c) In order to safeguard the interests of those born, it is desirable that the compelling logic of competing rights be set aside and that the families involved access the dimension of “understanding feelings” of “care” and the ethics of responsibility and solidarity towards those born, who one day will have to deal with an error which made their origins uncertain and the context of family life. Notwithstanding the need for two parental figures as reference points, it is not desirable for one of the two couples to be excluded from the life of those born.

Furthermore a number of reasons should, even through dialogic confrontation of the parties, favour the reciprocal exchange of “affectivity” towards the minors, so that the children can maintain a “meaningful relationship” with those who gave them life (in a genetic and gestational manner).

The trauma, the grief of separation suffered by the parents not recognised as such could be reduced by an awareness of the external error (for which the parents are not responsible) and the extraneousness of the genetic element of those born from the gestational one.

In addition, genetic mother and gestational mother, genetic father and legal father could consider “the greater suitability” of the embryos that gave

rise to pregnancy compared to the others, that did not result in any pregnancy. An entirely qualitative element, but if certified, it would have favoured the development of the pregnancy. It is also possible that the pregnancy is not only connected to the embryos but also to the co-occurrence of a more suitable gestational mother in anatomical and bio-hormonal terms.

The awareness of the genetic parents and the gestational mother to have contributed to the birth of the children should constitute the reason for the generosity requested of the two family units to ensure the children have a serene life, conflict aside: this generosity could be strengthened through mutual gratitude, respect and collaboration placing the primacy of the interests of the children as a guiding criterion, this means not sharp-cutting the links between these children and, alternatively, between the genetic parents and the legal ones.

As in other family situations, in view of the interests of the minor, there are legal means to protect the child in the case of exclusionary behaviours that are prejudicial for them occurring in one family nucleus in relation to the other, for example by providing the right to visit. There could also be a spontaneous agreement between the parties involved, recognised by the judge according to the principle of the best interest of the child.

d) In the context of the rights of the child, there is also the additional and essential interest of the couples to know the error and for those born to know their origins (mode of conception and gestation) through filters and appropriate criteria (proportionality, sustainability, importance, relevance, etc.) and, if necessary with the aid of qualified specialist psychological counselling in the different stages of their growth, if it is deemed necessary.

The NBC has already had occasion to recommend, in another Opinion (*Knowing one's biological origins in heterologous medically assisted procreation*, 2011) the right of the newborn to know the truth regarding their conception and their biological ancestry in its general aspects. It is all the more justified for the parents with whom those born live to be required to disclose to their children the truth about the manner of conception.

In these cases, the hypothesis of the child being denied the opportunity to know the personal details of the genetic parents and the gestational mother, is undesirable. This full disclosure on the part of the centre where the procedure is recorded about the origins of the newborn and the couples involved in the error may be authorised by the competent judicial organs

and is considered necessary not only for the reconstruction of the personal identity of those born, but also in order to allow the couples to promote the cooperation called for above.

e) Lastly, the NBC recommends that, with the spread of these techniques, there should be an increase in the safety procedures, by means of effective regulations in order to avoid errors. It highlights the need to strictly follow the regulations in terms of quality, safety and traceability on the biological material of human origin in particular gametes and embryos as drawn up by the European provisions transposed into Italian national law. While human error can never be completely avoided, at the same time it is only through compliance to the safety procedures that our regulations have drawn out with certainty and in detail that the likelihood of such errors occurring is minimised. The breaching of rules by facilities and regional administrations increases the probability of error of individual operators. Within such a delicate environment as that of *in vitro* fertilisation where human lives are at stake - couples, the unborn - every single “adverse event” can have serious and traumatic consequences which are extremely problematic from the ethical and legal viewpoint.

A further general aspect to be considered regards the ways in which the couples involved in this adverse event find out about it. Usually this occurs through normal monitoring of the health status of fetuses, particularly in order to exclude the presence of chromosomal Aneuploidy.

The literature on incidental findings during the course of genetic testing is extensive and the right to know or not to know is still a matter of debate. In these specific cases, the problem is even more complex as it relates to a type of information that may not have specifically been requested, involving other parents. However, it is expected to be in the interests of those born (any medical reasons and knowledge of their genetic origins) both in the interests of the gestational mother and the legal father, especially considering that the mother on the basis of the information obtained could have chosen to terminate the pregnancy.

The complexity of such circumstances recommend that the error should be communicated clearly and in a timely manner; it should not be the geneticist, alone, to assume the responsibility of identifying the most appropriate behaviour to be adopted towards the couples, entrusting it to a molecular report integrated by information provided in the post-test genetic

counselling, rather, it is the Ethics Committee of the Centre, through carefully studied policies and procedures that should take charge and debate and decide the mode of communication that is most appropriate to the specific circumstances in the interests of the parties concerned.

Personal remarks

A personal remark by Prof. Francesco D'Agostino

I would like to explain in this note the reasons why I voted against (mine being the only vote against!) the document drawn up by the NBC on the well known adverse event, which took place at the “Pertini Hospital of Rome”, as a result of which a woman who had asked along with her husband and in full compliance with the Law 40/2004, to access homologous in vitro fertilisation, was implanted with two embryos in her uterus that were genetically generated by another man and another woman (and for them, however, heterologous embryo implantation did not lead to the start of a pregnancy).

I will summarise my comments in less than ten points.

1. The NBC has considered the ethical question of the conflict between biological maternity and gestational maternity to be undecidable. This is however a badly-posed question, because it does not exist on an ethical level, since the determination of maternity is not ethical but factual. Ever since the new techniques of MAP have enabled the multiplication of maternal figures (so now there is a common distinction between the genetic mother and the uterine mother and similarly both of these can be distinguished from the possible social mother) we must resign ourselves to the fact that there is no longer a unique mother figure (the same is true with reference to the male, since we cannot fail to distinguish, always within the context of MAP, the genetic father from a possible social father). Those who feel repugnance for the multiplication of maternal figures, seek to answer the question of who the true mother is within the most extreme practices of MAP, but they are asking themselves the wrong question, because in the context of manipulation of maternity all the women involved are true mothers, each one on her own level (even the social mother, who does not provide either the oocyte, or lend her uterus for pregnancy, should be considered a true mother, because without her intervention the future child would neither have been conceived nor given birth to). The real question that should be asked is not who

the true mother is, but which of the women who have contributed in different capacities to the process of procreation is to be ethically, socially and legally considered the mother.

2. The NBC declaring the “undecidability” of the case - has intentionally and explicitly limited itself to the bioethical level without entering into juridical and social evaluations; but assessing the merits of these evaluations, in my opinion, was and is one of its specific duties, seeing as one of its tasks is to develop recommendations for possible legislative acts (according to the precise dictates of resolution No. 6-00038 approved on 07.05.1988, by which the House of Representatives engaged the Government to establish the NBC).

3. The biojuridical solution to the case, however, does not appear particularly complex: taking the baby from the mother who will give birth to it, to give the child to the genetic mother, appears legally and socially absurd, not because the expectant mother is better entitled as a mother in relation to the genetic mother, but because the nine months of gestation (an accepted fact!) create links between the gestational mother and the unborn child that cannot physically be created (except in imagination) between the genetic mother and the unborn child. For the NBC not to want to elaborate these simple observations and call for a law to confirm in any case the status of mother to the woman who gives birth to a child, seems to me frankly unacceptable; especially since this overt non-decision seems to allude to the recognition, on the part of the NBC itself, of its institutional superfluity.

4. If it is established as a fundamental biojuridical principle that maternity which must obtain social recognition can only be gestational, it easily follows that in the best interest of the child the husband of the woman should nevertheless be recognised as the legal father of the unborn child, if, of course, he grants his consent.

5. Moreover, even stopping merely on the bioethical level, and intentionally excluding the biojuridical level, it seems very problematical to support, as the NBC does, that an ethical choice (any ethical choice!) is undecidable. It is possible to argue, in exceptional cases, that are extreme, or even simply very complex, that whoever has to choose is not able to do so or is not competent to do so: this is the traditional case, which, all things considered banal, where one feels the “need to resort to” the intervention

of the wise, capable of bringing light into the darkness. A variation of this case is the one for which the elaboration of an extraordinarily complex ethical issue may take a long time, sometimes, unfortunately, even more time than is actually available, in a case that requires quick decisions (just as is the case of the adverse event at the Pertini). In the history of moral philosophy, those who love case histories have found themselves countless times faced with complexities of this kind. The NBC could have, with an act of the utmost intellectual honesty, recognised that they needed a long time to carefully investigate and resolve the issue; they could also have asked to integrate among its members other scholars with more and better skills than those of the institutional members of the Committee. They did not want to do so.

6. Nor can appeal be made to the category of tragedy to properly set this issue. Tragic is meant as the opposite of epic: while we witness in the epic the conflict between good and evil, between just and the unjust, or between right and wrong, in tragedy the conflict is always between good. Those who love Greek literature know just how dramatic the results of tragedies are; but they also know that, in principle, a solution to the conflict exists (even if, as happens so often in Euripides, the solution is often entrusted to the decisive words of a deity). There cannot fail to be a solution, because between the conflicts of good one will have to be axiologically prevalent over the other, since it is only on this condition that tragedy is credible. Otherwise, the only logical solution to the tragic conflict is the one that is entrusted to the prevailing force of one of its subjects in competition; but when a conflict is resolved by force its tragedy disappears and only the blind brutality of violence without good reason remains on the scene.

7. To believe, as the NBC did, that a matter (in our case, the ethical conflict between the two mothers) is in se and per se not resolvable introduces within bioethics, for the NBC is in some ways the institutional custodian of bioethics, a disquieting guest (as Nietzsche said), that is the germ of ethical nihilism. Nihilism can be absolute, when one does not believe in the existence of good and evil. Instead we may talk about moderate nihilism, when one considers that it is not within the possibilities of human reasoning to distinguish good from evil. The reduction of ethical issues to subjective, emotional, psychological, and utilitarian attitudes falls within the logic of nihilism. Via this reductionism it is quite possible, even for the nihilists, to

unravel many ethical conflicts, but not through good use of ethics: e.g. by approaching the party that suffers most emotionally or that psychologically attracts greatest sympathy or the party with the most conspicuous interests at stake. But most of the time nihilism concludes with a judgment of non liquet (i.e. not clear): the formula that identifies, starting from Roman law to this day, in the theory of law the denial of justice by an incompetent or lazy judge who refuses to issue a judgment. Certainly, deciding is sometimes very difficult and produces conflicts and ideological lacerations: as shown by the very Latin etymology of the verb to decide, which takes us back to cutting. An honest decision, although very painful, is however noble; a non decision is, instead, and unfortunately a sign of moral weakness (if not pusillanimity). Far too many times, the NBC has let itself be seduced by this temptation, which instead should be boldly rejected, restricting itself to merely recording the various ethical options existing within it, without taking any formal position either way.

8. Added to this is the fact that, believing it to be impossible to disembroil the ethical knot of the two mothers, the NBC sent the legislator, albeit indirectly, a potentially highly dangerous, although seemingly reassuring, message: any decision the legislator may take to guarantee the right to two parental figures to the children born as a result of “adverse events” will always be justified. The legislature is therefore relieved of the obligation to provide good reasons for its legislative choices or for its possible eventual inertia and indeed, if such an authoritative committee like the NBC is unable to formulate these good reasons, why should it be expected of a parliamentary assembly? Added to this ethical nihilism is a genuine legal nihilism, understood as the doctrine that insists on presenting legislative output not as based on the promotion of common good, but merely on the potestative will of those holding power.

9. I should add that the final considerations of the NBC, the exhortations to both couples to discard all confrontational attitudes and to operate for the overriding good of the children, are indeed very noble and beautiful. However, they are also, and unfortunately, very abstract, as generally are all the moral exhortations expressed by beautiful souls. I take note, following the work which has led, in the plenary session, to the unanimous approval of this document, with my one vote against, that currently all the souls in the NBC are beautiful, except mine.

A personal remark by Prof. Carlo Flamigni

While agreeing substantially with the NBC's Opinion on the involuntary exchange of embryos, I believe that certain aspects of this document could have been much more significant and I would like to add some brief considerations on what seem to me the most important points.

The Opinion makes clear that "it is not among the tasks of the NBC to deal with the specific case as regards its technical errors, but to examine in general terms the bioethical profiles that emerge from these events": this issue deserved better argumentation and the Committee could have transmitted a more realistic perspective of the human error: there is no doubt that this is a very troublesome event (even dramatic in some cases - but certainly not in this case) and it must be prevented by taking the utmost care, however, the inevitable connection with the arrival of new techniques and modern instruments of care as well as more generally with the advance of science, cannot be ignored. So, for example, in the Rome of the Caesars medical errors related to the administration of antibiotics and the doses of radiation were particularly unlikely: I understand that some people might consider banning these techniques, because of susceptibility, but I have the feeling that patients with pneumonia and cancer would be opposed to this. Moreover, those who can rely on a clinical experience of more than half a century certainly remember the times in which many women avoided giving birth in public hospitals because they were frightened by the possibility of the babies being exchanged in obstetric wards. I do not think that this "sensational" error in the Roman hospital would have raised as much disconsolate lamentation if it had occurred in one of the Tobriand islands, where animism still predominates and where children are produced through the intervention of the spirit of their ancestors, or among Australian aborigines, who still believe the "wandering baby" legend.

In reality one cannot forget that the impact of human error is different depending on the context in which it occurs and that the assessment that it is given is heavily dependent on the historical moment and the benchmarks adopted for judgment. The specific human error that is the basis of the NBC's Opinion would have been given a different evaluation if a different kind of family model had been taken as valid. There are a number of kinds of family models which are widespread and sometimes in conflict with one another, this aspect should have been better considered. It is interesting to

note in this respect that in 1890 William James wrote: “The natural institution of motherhood and fatherhood does not exist and is just a myth much emphasised in the West. It is a statement that focuses on a certain view of man, typical of our society, where science and medicine in particular, claim to have the key to our identity. One should instead reflect on the fact that this claim is just an illusion, or more precisely, the myth upon which, in the West, the image of motherhood and fatherhood has been based. In fact, in other parts of the world, other cultures have created very different myths regarding parenting. Therefore, as it is biologically true that pregnancy is the product of fertilisation of an ovum by a spermatozoon, in the same way it is wrong to derive any definition of fatherhood and motherhood, it is a symbolic definition and not a biological one. Plain common sense shows, however that, when a man and a woman are expecting a baby and say they have conceived it together, the biological evidence for this is difficult to obtain and it is usually just their word that asserts this as true and that the fecundating spermatozoon is not of a different origin.” (Principles of psychology 1890). James went on to cite a large number of different models of family and concluded that the parents of a child are those indicated by society. Now as then, anthropologists and sociologists mainly agree in saying that our traditional model of parenting (which among other things, has long been in crisis for cultural reasons) is not the only one possible, as numerous empirical studies have long confirmed. In modern human society there can be traced different models of social inclusion of biological fact, different modes of thinking of how one can be a father and mother and it is therefore possible to imagine that even on this issue there is under way a clash of paradigms, with the consequences that are usual in such circumstances: the protest of those who are faithful to the old, the pressures those who support the new, the many (mostly useless) attempts at mediation.

Anthropologists and sociologists say, in essence, that the natural institution of motherhood and fatherhood is questionable, so that it calls into question the very existence of a true parental instinct, expressed in purely biological terms and believing rather that it represents if anything a myth which the West has emphasised. This myth focuses on a particular vision of man and claims to define our identity according to it. To imagine it possible to derive definitions of a purely symbolic nature from biological events, has, in reality, been proven to be totally wrong, as I believe everyone knows.

Today the error underlying the exchange has caused so much uproar because even in our society there is an ongoing conflict between the traditional family model and a new and different model, based on a paradigm that has been proposed to us for at least twenty years, connected with new ways of generating that call on the radical transformation of the relationships of kinship and the way to consider filiation and parenting. In this regard, I can cite some interesting examples that cannot be ignored: in the USA a growing number of very young women leave their egg cells refrigerated with the intention of retrieving them 20 years later, thus escaping the social punishment that men continue to inflict upon women; in many laboratories there is experimentation with ectogenesis that will allow women to avoid the slavery of pregnancy; in many Infertility treatment centres ovum donation is automatically offered in a large number of circumstances and virtually no women refuse; in 2013 the US Supreme Court declared illegal the Defense of marriage act, which prevented the recognition of gay marriages. I'm not asking anyone to accept the hypothesis that this new paradigm is changing many things in the world, I am asking everyone not to ignore it and discuss it in view of its importance and the need to compare it with serenity to the present paradigm, already deeply disturbed by the new rules on voluntary abortion and divorce and the finding that millions of children are raised successfully by a single parent. It would also have provided the opportunity to examine the moral implications of the possible acceptance of this new model, an analysis that should take into consideration the observations of the Courts of Justice which tells us that ethical rules should be formed on the basis of changes in the common sense of morals and not in accordance with a presumed "natural law" or traditions that are no longer appropriate. I approve the contribution because it stands in continuity with what I pointed out, but I reiterate that if the NBC had examined the aspects of the problem that I have tried to highlight, its contribution to the current debate would have been significantly greater. My hope is that there is a commitment to do so with an outlook open to the innovation that scientific progress puts at our disposal.

A personal remark by Prof. Marianna Gensabella

While substantially adhering to the structure of the Opinion Bioethical considerations on the involuntary exchange of embryos, the writer wishes to

propose some elements for argumentation and reflection on what has already been successfully exposed in the document.

The case of involuntary exchange of embryos whose Opinion examines its bioethical profiles raises for ethics and law issues of great complexity, both for their novelty, and for their differing from the will of the subjects whose interests it would like to protect. While supporting the conviction expressed in the Opinion of the extreme difficulty of deciding which interests must take priority, it is considered possible to indicate certain paths of reasonableness to find agreement, not least because their exclusion would undermine the interests of those involved.

First of all, it should be pointed out that here there will not be any priorities established between the two parental couples and their alleged right to the child: there is in fact no right to the child but the desire for parenthood, a licit desire, which can be called natural in the strong and full sense of the term, as it is the desire for life and birth. All four subjects involved in the case which examines the bioethical profiles are driven by this desire and resort to procreation techniques in the homologous form and therefore pursue a parental project following the traditional paradigm: a heterosexual couple married or cohabiting, that wants a child “of their own”, according to a social/legal bond that also corresponds to the genetic one. All four have a desire, which can also be described as a primary interest: for the embryos to be born. This interest on the part of the conceived is configured as the “right to life”.

It is clear that this interest/right can be protected only by the pregnant mother, or the woman who has had, even through error, the implantation of the embryo. It is therefore necessary, regardless of any option of principle in favour of the gestational mother in relation to the genetic mother, to start from the latter’s consent to parenthood, this is because, “in fact”, the same error gives her, like any mother who discovers to be pregnant, the responsibility for the choice of saying yes or no to pregnancy. It is essential to start from her consent to the implant and make the most appropriate choices because that consent which is the “most part” of the responsibility of motherhood, is confirmed in a free and conscious manner, even after becoming aware of the exchange of embryos. As is pointed out in the Opinion in the part in favour of the gestational mother, any decision addressing an involuntary restitution of those born, would undermine her acceptance and encourage her refusal of pregnancy, which the current legal system allows.

But what are the choices facing “this” gestational mother? Though it is clear we must respect her as a person, and not regard her as a mere incubator, but give honour to her consent, what is not clear, given the splitting of the maternal figure made possible by new procreation techniques and the situation in which she finds herself, is, which “type” of maternity this can be related to? The involuntary change in the parental project pursued with her husband or partner is not comparable to the transition from a homologous IVF to a heterologous IVF: the embryos in her womb are not the fruit of heterologous and do not genetically belong to her or to her companion. This situation cannot even be considered analogous to that of a “surrogate mother” - not foreseen by our legal system and bioethically highly controversial - that has given her consent to make her uterus available for the embryos of others: indeed at the time of the implantation she was pursuing “her” parental project, clearly and consciously directed to a homologous IVF. The condition which comes the nearest is the one, not provided for by our legal system, but foreshadowed by the NBC’s Opinion in 2005, Adoption for the birth of cryopreserved and residual embryos obtained by medically assisted procreation (MAP). In that Opinion, designed to meet the right to life of surplus embryos that are abandoned and the desire for parenthood of infertile couples, maternity takes the peculiar form of adoption before birth and for birth. The analogy with the gestational mother carrying, by error, in her womb embryos of another couple, leaves room for a certain difference: in her case the embryos are not “abandoned”, but “exchanged” and yet still wanted by the genetic parents. The analogy, however, stands in regard to the intention for two reasons: to ensure the right to life of the embryos and fulfilment of one’s desire for parenthood, which for women takes the peculiar form of passage through the body. It still stands in regard to the peculiar condition of having in her womb embryos that genetically- in contrast to heterologous IVF - are foreign to her and her husband/partner but they can be “adopted” by both. This would involve transforming the first consent to homologous IVF into a second consent for adoption before birth and for birth.

However, another option also remains open, which from the ethical point of view has its justifications: that the gestational mother chooses to continue the pregnancy as fostering for birth and prior to birth, fostering that is not only aimed at birth but that ends at birth. The special situation created by the error requires both ethics and law to move in new territory that is nei-

ther that of homologous fertilization, from which the parental project had commenced, nor that of heterologous or even that of a surrogate mother, being foreign to the parental project. This makes it possible to think of these two forms and the possibility that both may be supported by the agreement of the partner/husband who shared the parental project.

In the first case the gestational mother by adopting the embryos that are not hers, takes on the maternity and it does not seem possible, for the gestational bond on which the opinion focuses in the part in favour of the gestational mother, to separate this relationship in an authoritative manner. This solution is not included at present in our legal system, it is also excluded from bioethics which respects the “dignity” of the gestational mother as a person.

It should, however, leave open the possibility that the gestational mother, who considers important for her, her partner/husband or responsibly evaluates the genetic bond as important for the children, chooses to be the foster mother for birth and until birth. If the validity of this option is recognised on the bioethical front, one could think of solutions on the biojuridical front, given the exceptional nature of the situation, innovating compared to what is currently foreseen by the legal system and taking into account the wishes of the genetic parents to recognise those born; providing for the possibility at the moment of birth for the child not to be abandoned and therefore be in a state of adoption, but to be immediately recognised by the genetic parents. Again this possibility should not involve the anonymity of the mother, who, in the interests of the newborn regarding the truth about one’s origins, should be able to be recognised/known as the person that consented to the birth.

The second priority concerns the protection of the interests of those born, from which the Opinion rightly proposes to start. To impose it, even prior to the law, is ethics itself and the principle of responsibility that finds in the parental paradigm its first, fundamental application. The Opinion highlights two fundamental interests of those born: one is to have a certain parental reference point and the other regards the truth about one’s origins.

As regards the first, one must note how in the Opinion there is talk of “two parents” and not “a parental couple”. The Opinion indicates in fact, without expressing preferences, three possibilities for parental reference points: the gestational mother and her partner or husband, the genetic par-

ents, but even, following the parenting that could be recognised in the existing legal system, the gestational mother and the genetic father. This last possibility breaks the unity of the couple that embarked on the parental project and prefigures cross-parenting. The traditional parental paradigm, that has been a point of reference for the project of both couples, becomes radically transformed, but it is detrimental also to the interests of those born to grow up in “a” family. Who will the children live with? With the gestational mother or the genetic father? Their situation is similar to that of the children of divorced couples but with one difference, that is in no way small, the initial complete extraneousness of the parents.

The same parental project that has as its ethical reference not only the principle of responsibility but its application in a shared responsibility, thought out and experienced together, would be undermined from the start. The negative repercussions on all those involved seem evident: on the children who would lack a family environment that gives as far as possible shared educational reference points; on those who are recognised as parents, as they would bear the suffering of living parenting that is on the one hand crossed with a stranger, and on the other that is separate from their partner; on their partners or spouses excluded from the parenting; These difficulties do not appear, in the opinion of the writer, surmountable and impose its exclusion, as it is clearly not feasible because detrimental to the interests of all those involved, the third hypothesis sees as a parental reference point the gestational mother and the genetic father.

Nor is it worth maintaining such a hypothesis only on the grounds that it would guarantee with certainty the possibility of “including” both of the parental couples, recognising as parent “one” of its elements. Indeed, there would be, in an attempt to include everyone, a splitting of the couple that gives rise to and supports the fulfilment of the parental project. It is as if to the involuntary splitting of motherhood between the genetic mother and the gestational mother one responds with the splitting of parenthood, which far from being an attempt to remedy the error, would only perpetuate the consequences.

The proper recognition of the double bond of those born with both parental couples must be achieved by other means, while protecting interests regarding the truth about origins and thinking, as a part of the Opinion suggests, of forms of emotional relationships between the child and the couple

to whom parental responsibility is not recognised from the legal and educational standpoint: forms starting from “rights of access” that could be thought of and defined by means of new instruments utilised by biolaw as para-parental.

Salvatore Amato subscribed to this personal remark.

LAZIO REGION
Regional Health Directorate and Socio-sanitary Integration
Institutional Legal Regulations Area, and Interface with the Regional Advocacy

Prot. No. 260 685

Rome, 06 May 2014

To the President of The National Bioethics Committee
Prof. Francesco Paolo Casavola
Via Della Mercede, 96 - 00187 Rome

SUBJECT: The adverse event that occurred from the 4th to 6th December 2013 at the hospital Sandro Pertini - ASL RMB

With reference to the very serious events that occurred at the hospital Sandro Pertini -ASL RMB in relation to Medically Assisted Procreation (MAP) and made the subject of news releases on the 12th and 13th April of last month, it is considered appropriate to report to the National Bioethics Committee the above adverse event presumably linked to treatment induced by ICSI (Intra Cytoplasmic Sperm Injection) practiced in the UOSD of Physiopathology of Reproduction and Treatment of Sterility at the Sandro Pertini Hospital on 4th December (pick up date) and 6th December 2013 (transfer date).

Following the above ICSI treatment one of the couples involved achieved a twin pregnancy and following several diagnostic tests performed at the laboratory Sant' Anna ASL RMA there was the subsequent discovery of the incompatibility of the DNA profiles of both parents with both fetuses.

In view of the legal and ethical implications related to the matter and the profiles of responsibility that can be configured, it is considered appropriate to send this communication along with the report and documentation acquired at the Pertini, already sent to the President of the Lazio Region (att. 1).

The foregoing so that the aforementioned Committee may issue an opinion or provide a response in accordance with the Regulations approved on November 28, 2008, as supplemented by the guidelines of 24 April 2009.

We remain available for any further clarification and/or supplements (which can be obtained directly from the Area Manager, Dr. Cristina Matranga, 06/51684274) awaiting your response.

With best regards

THE AREA MANAGER
(Dr. Cristina Matranga)

THE GENERAL DIRECTOR
(Dr. Flori Degrassi)

Presidenza del Consiglio dei Ministri



**DECLARATION ON CLINICAL TRIALS
AND THE CONFERRAL TO THE EUROPEAN
COMMISSIONER FOR HEALTH AND CONSUMER
POLICY OF COMPETENCES ON THE EUROPEAN
MEDICINES AGENCY (EMA)**

24 October 2014

Preamble

At the moment when the European Commission has taken office²²², the conferral to the European Commissioner for Health and Consumer Policy of competences on the European Medicines Agency (EMA) and, more generally, on clinical trials, drugs, pharmaceuticals and devices has been confirmed. At the beginning, such conferral has been called into question, so that it was supposed to move Unit B2 (*Health Technology and Cosmetics*), D5 (*Medicinal Products - Authorisations, European Medicines Agency EMA*) and D6 (*Medical Products - Quality, Safety and Efficacy*) from DG Health and Consumers (DG SANCO) to DG Enterprise and Industry (DG ENTR)²²³. Clinical trials, the placing on the market of new drugs, the report of suspected unexpected serious adverse reactions and EU database could have been, at least in this field, included in the competences of the European Commissioner for Internal Market, Industry, Entrepreneurship and SMEs²²⁴. This circumstance was already known at a European level. The EMA was set up under Regulation (EC) No. 726/2004 and remained within the portfolio of Industry until 2010, when its sphere of competence moved towards the then-European Commissioner for Health and Consumer Policy. In previous years, many experts in the field and Patients Associations criticized this transfer, for it was considered inappropriate and in opposition with the institutional structure of the most important countries of the European Union.

Declaration

The NBC shares the European decision on the conferral of competences on EMA and, more generally, on clinical trials. In that respect, it considers important to underline the reasons why such institutional structure is highly significant.

Drugs are not, even symbolically, a mere consumer good, otherwise they will lose, or at least lessen, their main meaning as an instrument of health protection in an integrated system. The current situation of the com-

²²² 1st November 2014.

²²³ Furthermore, DG ENTR merged with DG MARKT (Directorate General for the Internal Market and Services).

²²⁴ Small and Medium-sized Enterprises.

petences has the merit to avoid a highly potential conflict of interest among industry, guarantee authority, triers and patients/ EU citizens, who have the right to see the impartiality and independence of those administrative structures involved in a field of a highly public and personal relevance safeguarded.

The Directorates-General of the European Commission are departments with a total managerial autonomy, while the general and political powers are a question of the Commissioner in charge. A possible repetition of the competences on EMA to the European Commissioner for Internal Market, Industry, Entrepreneurship and SMEs would have given to the latter the definition of priorities and the overall strategy of the European Union on clinical trial of drugs, consistent with its institutional mandate.

Furthermore, this problem became worse due to the recent approval of the Regulation (EU) No. 536/2014 of the European Parliament and of the Council 16th April 2014 on clinical trial of medicinal products for human use, which abrogates Directive 2001/20/EC, though including detailed guarantee procedures and calls of ethics. In terms of a necessary perspective aiming at a simplification of the procedure, harmonization and promotion of European competitiveness at international level, the text shows several ethical problems and seems, at least partially, more favourable to industry and market efficiency rather than to the protection of rights, safety, dignity and well-being of patients.

The NBC is aware that health care management is not directly included in the initial EU Treaties, and, therefore, those elements of a European centralisation of health care fall within the perspective of a single European market. However, Article 168 of the EU Treaty in 2010 states that “*a high level of human health protection shall be ensured in the definition and implementation of all the Union’s policies and activities*”. Furthermore, developments in the laws and their procedures of the European Union (i.e. the Charter of Fundamental Rights of the European Union), as well as the increasingly strong emphasis placed on the rights of individuals and on the health protection of European citizens, justify the conferral of the competences in the field of clinical trial to the portfolio of Health.

For these reasons, the NBC:

- welcomes the conferral to DG SANCO of competences on EMA and its related activities;

- proposes that industry impartiality will be strengthened further through an EMA prevision of financial autonomy;
- expects the introduction and development of independent studies for the authorization of new drugs or new therapeutic indications;
- recommends that the above-said Regulation (EU) No. 536/2014 will be interpreted and applied in order to put patients' rights at the heart of the EU action.

The document was drafted by Prof. Cinzia Caporale, with the contribution of Prof. Silvio Garattini.

The document, discussed within the plenary, was voted and approved unanimously by those present, Profs. Salvatore Amato, Luisella Battaglia, Stefano Canestrari, Cinzia Caporale, Carlo Casonato, Antonio Da Re, Carlo Flamigni, Paola Frati, Silvio Garattini, Marianna Gensabella, Assunta Morresi, Demetrio Neri, Andrea Nicolussi, Laura Palazzani, Monica Toraldo di Francia and Grazia Zuffa.

The ex Officio members who joined are the following: Dr. Carla Bernasconi, Rosaria Conte and Carlo Petrini.

Among those who did not attend the plenary session, the following members have adhered to the Declaration: Carlo Caltagirone, Lorenzo d'Avack, Bruno Dallapiccola, Mario De Curtis, Rodolfo Proietti, Massimo Sargiacomo and Lucetta Scaraffia.