Presidenza del Consiglio dei Ministri

BIOETHICAL ASPECTS OF AESTHETIC AND RECONSTRUCTIVE SURGERY

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PRESENTATION

In the first part of the document, the NBC reflects on the limits of the legitimacy of requests for aesthetic surgery – which are ever-increasing in number - and in particular on the physician-patient relationship, in the context of the discussion on the many ethical, social and cultural factors that affect the change of attitude towards the body and an expansion of the concept of health in the subjective sense.

Since this intervention is not for strictly therapeutic purposes, the NBC reiterates application of the deontological standards that govern medical practice, which are - in this specific field - sometimes disregarded in favour of an accommodating compliance with the request expressed by the individual; it emphasises the unacceptability of disproportionate intervention, as it is excessively invasive or unnecessarily risky and inappropriate in relation to the possible benefits requested by the patient. In addition, the Committee believes that the licitness of intervention should be proportional to the balancing of risks and benefits and commensurate with the psycho-physical condition of the patient and the functionality of the affected organs, and the comprehensive information given to the patient, with the provision of adequate counselling, including also psychological advice.

As regards operating on minors and those lacking the capacity to consent, the NBC believes that there must be limits to licitness, except when this intervention is in their exclusive and objective interest in terms of health, especially in consideration of the period of adolescence. In particular, the NBC does not consider aesthetic surgery on children with Down syndrome to be legitimate, when its aim is the conformity to the social canons of 'normality', especially if it is invasive and painful, even considering that it is unlikely that these operations may be beneficial to individuals, frequently instead, it is possible that they accentuate rather than reduce personal uneasiness.

The opinion calls for the provision of appropriate social information and education regarding the risks and benefits of aesthetic surgery and greater rigour in the formation and professionalism of plastic surgeons, also aimed at including the understanding of the psychological and ethical issues related to this specific medical practice.

The second part of the document tackles the emerging bioethical issues in reconstructive surgery. This is a sector in continuous expansion and development which requires appropriate ethical reflection. With particular reference to face and limb transplantation - due to the experimental nature of these procedures and the fact that they are not essential for survival, the NBC recommends a careful assessment of the risks and benefits, in relation to general considerations of the improvement of the quality of life for the patient. Furthermore, appropriate counselling is considered necessary in advance of the surgery, and for a prolonged period (extended even to the family), because of the complex issues that affect the risks and benefits, accompanied by constant psychological monitoring of the recipient. Patients must be informed accurately and comprehensively of the risks to health and the severity of the anti-rejection

therapies and the fact that in any event they lead to a dependency on these drugs (with possible negative outcomes) that could even last a lifetime.

It is hoped that in the implementation of appropriate informed consent there will also be use of new information technologies, so as to promote the collection of information and knowledge through access to sites accredited by the competent public institutions, as well as the national and international registers in which the most recent studies in this field are published and where scientific publications generated from the study can be found. In addition, the NBC encourages public awareness campaigns for the donation of external organs and tissues, as normally takes place for the donation of internal ones. It also calls for, in this context, the possibility of integrating legislation providing for "partial" consent or dissent to external organ donation.

The subject was proposed by Prof. Umani Ronchi during the plenary session on 27th January 2011. The opinion was drawn up by Profs. Lorenzo d'Avack, Laura Palazzani and Giancarlo Umani Ronchi, with written contributions from Profs. Salvatore Amato, Antonio Da Re, Riccardo Di Segni, Marianna Gensabella, Assunta Morresi, Demetrio Neri, Andrea Nicolussi, Monica Toraldo di Francia.

In the drafting of the opinion valuable contributions were provided by the auditions in the plenary session by Prof. Nicolò Scuderi (Director of the Department of Plastic Surgery, University "La Sapienza" of Rome), by Dr. Francesca Romana Grippaudo (Plastic Surgeon Sant'Andrea Hospital in Rome) and by Dr. Anna Contardi (National Coordinator of the Italian Association of People with Down Syndrome) for the field of aesthetic surgery and by Prof. Giorgio Iannetti (Professor of Oral and Maxillofacial Surgery at the University of Rome "La Sapienza") and Prof. Marco Lanzetta (Director the Italian Institute of Hand Surgery) for the field of reconstructive surgery.

The opinion was voted in the plenary session of 21st June 2012 and published 5th July 2012.

Profs. S. Amato, L. Battaglia, F. D'Agostino, A. Da Re, L. d'Avack, E. Fattorini, M. Gensabella, A. Morresi, D. Neri, A. Nicolussi, L. Palazzani, V. Possenti, G. Umani Ronchi voted in favour. Prof. Claudia Mancina voted against. Profs. A. Bompiani, S. Canestrari, B. Dallapiccola, R. Di Segni, M.L. Di Pietro, R. Proietti, L. Scaraffia, M. Toraldo di Francia absent at the plenary session voted in favour.

The President
Prof. Francesco Paolo Casavola

DOCUMENT

1. Introduction

In the field of plastic surgery aesthetic surgery can be differentiated from reconstructive surgery.

Aesthetic surgery comprises operations that modify, correct or improve the aesthetic and functional aspect of the body. It is aimed at those who request medical intervention for the modification of parts of their body for purposes which are not always strictly therapeutic and that, more often than not, are motivated by desires and subjective needs to conform to a corporeal ideal.

Reconstructive surgery corrects malformations that are congenital or caused by trauma or demolition. These operations have the primary objective of restoring function and improving the appearance of patients with serious impairments, victims of significant trauma (car accidents, workplace accidents, animal bites, burns, ballistic injuries, etc.) or destructive pathologies. Autotransplantation can be performed on the outcomes but when this is not possible healthy tissue donated from cadavers can be implanted. It is technically a composite tissue allotransplantation of skin, bones, muscles, blood vessels and nerves. In reconstructive surgery there is an overlap of both aesthetic and therapeutic needs.

The issue of transsexualism will not be dealt with here, (which requires more extensive references to issues regarding sexual identity - regulated in Italy by Law No.164/1982), scarification and the request for limb amputation (which leads to a more complex treatment of psychiatric problems), the activities of skin *piercing* and tattooing and acts of self-creation (*body art or carnal art*).

From an ethical and juridical viewpoint, the issue of aesthetic and reconstructive surgery intersects on one hand with the vexed question of the status of the human body and on the other with the actual activity of the physician aimed at protecting the health of the patient.

2. Aesthetic surgery

2.1. Regarding the request made to the physician to modify one's body

The body as subjectivity, "the lived body" is what we are and carries on it the signs of what we have been: it is the body that bears the years that pass and the signs of the emotions that have marked and mark our existence. In this sense, our identity is always the identity of an 'incarnate being'.

We inhabit the world and relate 'to' others as a body-subject. The body which we are projects outwardly and this projection has a dual significance. It places us in contact with others, in an inter-subjective/inter-corporeal dimension, which allows us to build our identity. At the same time it is a vehicle of meaning that communicates what we want / would like the world to perceive about us. It 'is especially in this second function, that the body can be perceived differently in its outward manifestations, to the eyes of others, from what is experienced within our subjectivity: not an incarnate identity, but a "mask" that overlaps with that identity,

sometimes altering it, with consequences on the same experience that each person makes of himself and herself and their own sexed corporeal dimension, and at the same time with negative consequences on intersubjective relationships. In these cases there may emerge the 'need', a more or less induced need, to work on the external aspect of the body, that body as 'object' which 'appears' to the eyes of others: a process of 'objectification' of the body begins, in order to make it manageable, modifiable, malleable according to the desire for an identity which the body should reflect, according to the models accrued within intersubjective relationships, often based on social conditioning.

It should be borne in mind that there are multiple social factors that have influenced the new imaginaries that accompany the changing attitude towards the body and an increase in requests for aesthetic surgery. Among these one should mention: the tumultuous development of bio-technological innovation that always offers new possibilities for manipulation of the body opening up future scenarios of 'cosmetic genetics'; the profound changes in the interpersonal and professional relationships which impel towards external representation in social life and attention to 'appearance'; the emphasis on beauty that tends to become increasingly synonymous with well-being, youth, increased sexual pleasure and the subsequent need for this to last over time[1].

Supporting, these fantasies of freedom from the constraints that our being incarnate imposes on us is today's media culture (advertising, television programs, films, articles in newspapers and magazines, internet), allied with an increasingly pervasive business of beauty and fitness. The growing number of offers on the web for aesthetic surgery, capable of arousing clearly unrealistic expectations should be noted. These messages, influencing tastes and aesthetic canons convey the idea that it is on the body and its aesthetic dimension that social and economic interests converge. Those operating in this sector should be made aware of the risks that their messages can transmit.

It is possible then that men and women today turn to the aesthetic surgeon more and more often due to physiological and psychological needs, and even unconscious ones, but above all out of a desire for social integration in accordance with certain stereotypes. And it can not be denied that the relationship between aesthetics and emotional, social and family life can be very close, so much so that after an operation that has solved serious physiognomical problems, it can not be excluded that patients re-elaborate their own internal image in order to gain confidence in relationships with others as well as with themselves.

But the activation of models of beauty with their cultural and consumerist imperatives can also create negative effects, especially in the most vulnerable: growing insecurity in the face of the ageing process or simply somatic aspects that create individual differences compared with the dominant and uniforming aesthetic criteria.

Therefore, the increase in requests for aesthetic surgery stimulates and makes necessary the bioethical discussion on the limits of legitimacy of such a request especially in the relationship between the patient and the physician.

[1] Take 'aesthetic surgery on private parts' (vaginoplasty, hymenoplasty, cosmetic vaginal tightening, plastic phallus), widely advertised on many websites (female genital cosmetic surgery or FGCS).

In this context, inevitably, the theme of beauty intersects with that of health as the individual's request for body modification to the physician can not be detached from direct or indirect reference to the therapeutic dimension. There is, today, a trend towards the expansion of the concept of health with the accentuation of the subjectivist dimension, even following the definition of health of the World Health Organisation as a state of "complete physical, mental and social well-being"[2]. In this perspective, aesthetic surgical intervention would come under therapeutic treatments, in so far as a specific physical condition - regardless of objective pathological considerations - is perceived by the person concerned, on the psycho-social level, as the source of uneasiness and discomfort. Therefore those who ask the physician to transform their body to make it more beautiful (according to their ideal of beauty and health) believe they have a right to freedom and self-determination in the implementation and development of their personality, considering ' aesthetic health ' as a good not only to preserve and replenish, but to some extent, also to promote as a fundamental element of the identity of the individual, according to their own subjective desires and social relations[3].

The NBC, while noting that the current bioethical debate tends to question the clarity of the distinction between 'healthy / normal' and 'pathological / abnormal' and to welcome the co-existence within the context of health of subjective and objective dimensions, it intends to highlight in the specific area of aesthetic surgery the risks of an excessive relativisation and subjectivisation of the concept of health.

In this context, it is not possible to define a priori in a specific, exhaustive and definitive manner the limits of licitness of interventions (requested by the patient and carried out by the physician), to rigidly outline the distinction between the spheres of acceptability and unacceptability: nevertheless the need to reiterate the deontological obligations governing medical practice, at times annulled - in this specific area - in favour of a compliant implementation of the individual's request. Therefore, the NBC believes that in casuistry both the patient and the physician must respect the principles of proportionality and accuracy (assessment of physical and psychological condition of the patient, comprehensive information, informed consent, risk/benefit assessment-expectations). It is through these policies that it is possible to justify the licitness of the request and the resulting surgery as it is in the patient/physician relationship that a therapeutic aim is

[2] It is the definition of 1948, subsequently revised by the Ottawa Charter in 1984 ("the process that allows people to increase control over and improve their own health). Also the Charter of Fundamental Rights of the European Union (2000) believes that the interest in "physical integrity" must be measured,, more generally, in all the decisions that relate to the modification of the body, with the widest integrity of the individual (Art. 3).

[3] In Italy the right to self-determination over one's body, within the limits of Art. 5 Civil Code was claimed under Articles. 2, 13 and 32 of the Constitution. The Court of Cassation already in 1994 recognised that aesthetic surgery had a precise position, stating that "the typical function of medicine, identified in the care of the patient in order to cure disease, to reduce the injurious effects or, at least, alleviate the suffering it produces, safeguarding and protecting life, does not exclude the legitimacy of cosmetic surgery, whatever the psychological disorders that may result from an expanded view of the unpleasant aspects of one's body, it tends to improve only the aesthetics" (Cass. civ. n. 10014/1994, in "Foro it.", 1995, I, 2913). See also Cass. Civil Code. n. 9705/1997.

reached, in the broad sense. There must be exclusion of other requests for intervention distorted by the logic of 'desire' which may backfire on the same individuals who `desire` them and which represent a sort of 'aesthetic persistence' or mere exploitation of the body or dictated by psychiatric disorders (so-called dismorfofobia).

The specificity of these interventions means that public institutions are generally reluctant to contribute financially to the exercise of the right of patients to change their physical appearance for aesthetic purposes[4]. Moreover, it can not be forgotten that while the private system responds to a logic strictly related to insured risk and to the type of service provided (ratio which determines the premium paid, subject to the profit margin), the public system responds to a broader logic that must take into account, and mitigate, natural, social and economic inequalities and the need to ensure fundamental rights (right to protection of health), despite their inseparability from evaluations of an economic nature, given that resources are still limited.

2.2. The responsibility of the physician and informed consent

The responsibility of the surgeon in legal terms in aesthetic surgery has some peculiarities with respect to general professional liability. In reality, in so far as the aesthetic purpose differs from common therapeutic purposes, there can be a change in the importance of responsibility in the relationship with the patient and the sense of distribution of the risk inherent to the intervention and consequently also a change in the extent and method of informed consent.

In the analysis of the obligation that the doctor takes towards the patient it is an established principle that, in addition to having to comply with the rules of professional conduct, it includes the performing of professional activity necessary and useful to the specific case, according to criteria of appropriateness and medical expertise. Consequently the result, measured according to objective parameters, does not always and necessarily coincide with the satisfaction of the patient, since the satisfaction of the patient - may not be obtainable only and directly through the professional's behaviour - think of the recovery from an illness Therefore, in medical practice in general, this result should be evaluated so as not to discourage intervention for which there is a socially felt need and which, moreover, aims to achieve the protection of a fundamental value such as health itself. In addition, the particular significance of the activity carried out by the physician may advise us not to heighten his responsibility to the extent of his being made guarantor regarding risks extraneous to his actions.

Notwithstanding that even when the physician acts for aesthetic purposes he must measure his behaviour in relation to expertise and deontology, the given

[4] In Italy, the National Health Service has introduced, with effect from 1 July 2002, the "essential levels of assistance (LEA)" defined by Decree (DPCM) of 29.11.2001 establishing essential minimum services guaranteed in all the country. The LEA have comprised among the categories of the excluded services/benefits also aesthetic surgery not resulting from injury, disease or congenital malformation.

result could be assessed in a different manner. The moment that the operation is merely or mainly for aesthetic purposes the need to encourage these interventions may fall short or be less valuable socially. Consequently, a possible reduction in the physician's responsibility, arising from consideration of the correct behaviour comprehensive of the requested result, or by less serious evaluation of technical error in cases of special difficulty, should not be extended to services performed for merely (or mainly) aesthetic purposes, burdening the risks on the patient. In these cases, the interest of the professional to carry out his activity - for strictly economic reasons (in the case of a contractual tie with the patient) or indirect economic reasons (in the event that he is employed by a hospital) - is not offset by an objective need to protect the health of the patient/client.

The specificity of aesthetic surgery, which, as mentioned, is not an indispensable therapeutical intervention makes even more necessary the informed request (informed consent) of the patient, which includes each aspect of the justification for the intervention, together with the professional autonomy of the physician and his deontology.

As a result there is a need for special rigour and attention regarding the information given by the doctor. The NBC considers it necessary - in order to ensure the principle of non-maleficence - that the information must be complete and comprehensive, not only as regards the techniques of the operation, but also the consequences on health, possible benefits and risks, the expected results of the medical act in relation to the subjective expectations of the patient, verifying in a particularly scrupulous manner which part and how much of the information provided has been fully understood by the patient[5]. In this context it could be useful to indicate to the patient to obtain information online through accredited sites or by using means of verification (including questionnaires) of the understanding of information directed also at highlighting the real reasons that lead to the request for surgical intervention.

What is certain is that the physician should not only have the role of a technician who works on imperfections and improves them, but he must also have the sensitivity and the psychological preparation to understand when and if operating is essential. The aesthetic surgeon should therefore not neglect, even indicating to the patient the possible need for an extended consultation, considering the personality of the applicant, evaluating, even in this respect, the feasibility of the treatment.

[5] A recommendation endorsed the Court of Cassation: "In terms of surgery, so the patient is able to exercise their right, that the Constitution gives him to choose whether or not to undergo surgery, it is incumbent on the doctor of a specific duty of information about the benefits and procedures of the transaction, as well as any foreseeable risks in the post-operative stage; a duty that in the field of aesthetic surgery, where it is required that the patient will achieve a real improvement in his overall physical appearance, it is particularly meaningful, with the consequence that the omission of that duty, regardless of the success of the intervention and independently whatever the nature of the obligation of performance of professional services, shall not relieve the doctor of liability, whether in contract, tort, if it does occur - as a result of the intervention - a harmful event" (Cass. civ, n. 9705/1997). The principle is always valid (Cass. civ., No. 14638/2004.) that in any event informed consent is necessary: "In the contract for the provision of intellectual work between the surgeon and the patient, the practitioner, even when the object of his performance is only the means and not of result, has the duty to inform the patient of the nature of the intervention, the scope and extent of its results and the possibilities and probabilities of the results to be obtained"

In addition, despite the capacity of aesthetic surgery to significantly reduce dysmorphia, it is not always able to remove the condition of malaise that underlies it, so that the problem can recur after even a short period of time with the claim to additional, unnecessary operations. It is in this way that the risk/benefit relationship is broken or, more exactly, it is altered and becomes unbalanced - within the context of the therapeutic alliance - which is the deontological and ethical foundation of the licitness of the treatment; in these cases the physician should, for deontological and ethical reasons, manifest unwillingness, without however abandoning the patient but suggesting other less invasive possible solutions.

Therefore, it is essential to carry out a balanced evaluation on a case by case basis, as it is often difficult to know the limits of the therapeutic measures, able to help those requesting surgery to overcome their uneasiness.

In this context, the risk of the patient ending up in inexperienced hands or in the workshop of a 'merchant of operations' or of being transformed from a "patient" to a mere "customer" is an increasingly present and worrying reality. There is a fine line between licitness and collusion in the field of aesthetic surgery whenever the physician tends to encourage the unrealistic illusions of the individual with insufficiently motivated operations. Consequently, therefore, there is a need for particular rigour and attention in the information given by the doctor even as regards the non-therapeutic nature of the act. The aim of specialists should be to offer their expertise to help solve the patient's problem, not the selling of a service without their being concerned whether it is the most appropriate.

Furthermore, it is cause for concern that in Italy - according to a survey conducted by the Italian Society of Plastic Reconstructive and Aesthetic Surgery (Sicpre) - those who work in the business of "aesthetic touch-ups" are estimated to be much greater in number than the members of the Society itself, with the possible risk of there being many "improvised" professionals. As with many other medical specialties, this is due to the regulations for practicing the profession, which in our country is very permissive, as anyone who has a degree in Medicine, is licensed to practice, and registered with the Order of Physicians, can in theory undertake medical activities which require a high level of specialisation. Alongside this theoretical possibility one must contrast the control of the schools of specialisation and professional societies, and correctly informing the users of the general public. For this purpose the NBC recommends that the advertising of surgical intervention and the obtained and obtainable results in this field should take place on accredited websites which are certified by competent public institutions.

2.3. The protection of minors and those incapable of giving consent

International charters generally recommend that in any medical procedure, involving individuals who do not have the capacity to consent, there must be special protection, based on the ethical and legal standards adopted by States.

In the present case of aesthetic surgery, as already mentioned, it is not generally esssential medical intervention, let alone life-saving intervention, and therefore in the case of a person who is incapable of giving consent this

shortcoming can not in any way be redressed, given the absence of connection between the authorisation of the person excercising power (usually the parents) and an initiative that brings real and direct benefit to the health of the incapacitated person. Acts of this kind come under "highly personal acts," that can not be taken by someone other than the person directly concerned, to be precise, it is not possible to be substituted by anyone else neither by parents nor by the legal representative.

Should anyone want to take into account that the incapacity to act, or the inability to perform legal acts until the age of 18, is essentially attributable to acts related to the sphere of assets, it is possible to expand the decision-making autonomy of the minor who has reached sufficient capacity to take a conscious decision (the so-called older-minor), regarding tending to his “existential” interests. On the other hand, we must also take into consideration the particular psychological relevance that in adolescence some aesthetic conditions can have, which can be experienced as intolerable and the cause of suffering and uneasiness.

To guarantee the formation and awareness of consent there should, however, be precise circumstances. The authorisation of the parents is primary, as they qualify as a *medium* of the child’s will, being attentive to precise information and sufficiently certain that the motives put forward for surgery are not completely disconnected from the therapeutic context or conditioned by an unreal expectation, or dictated by a non-objective and proportionate perception of the world and the social ideals surrounding the teenager. Other guarantees can be obtained through the provision of specific counselling, with trained personnel giving information commensurate with understanding about the risks and benefits of the intervention.

The concern that forms of distress and anxiety may arise in adolescents regarding the development of their body, the possible distorted perception of their body appearance, leads the NBC to support the choice made by certain legislations, such as the Spanish one, to ban, during certain times, in the context of audio-visual programs forms of advertising that may lead to the rejection of their body image and facilitate social exclusion because of a physical condition determined by weight or aesthetic factors. Also considered highly appropriate by the NBC is the legislative prohibition to carry out breast implants on minors for purely aesthetic reasons, and the establishing of information requirements for patients who wish to undergo such operations or who approach aesthetic surgery too soon at an age when the body has not yet completed its development[6].

In this context, the issue of aesthetic surgery on minors with Down syndrome gains bioethical significance, normally this syndrome, as well as altering physical appearance, causes mental retardation, usually with a mild to moderate degree of impairment of several cognitive areas. For this disability there is a recurrence -

[6] On 22 May 2012 the Parliament approved the law establishing national and regional registries of breast implants, information obligations to patients, as well as ban on breast plastic surgery in underage patients (Chamber Act No. 3703-B). Exceptions are cases of malformations or breast diseases, operations guaranteed by the National Health Service. The register of the prosthesis must allow full traceability of materials used and the follow-up of patients. The available data, guaranteed by suitable privacy, will enable monitoring of the patient over time, and may provide useful information to prepare guidelines on the use of safer and more effective. diagnostic techniques.

indeed to some extent, even an amplification of - the problem of obtaining valid consent as well as the many limitations already set out above with regard to the minor or incapable adult. It must be considered that the decision to take the path of aesthetic surgery even for therapeutic purposes (improvement of respiratory dynamics, feeding and language), is based not on the will of the minor or incapacitated person with Down syndrome, but only on that of the parents. The NBC believes that surgery that complies with functional type needs must be considered legitimate, as is the case for any intervention carried out on the minor or incapable person that proves necessary for ascertained physical reasons. However, great caution is necessary in implementing these operations, given their complexity and painfulness, their non-permanent nature (requiring further intervention during growth) and given that certain traits and physical defects can, in turn, diminish with the growth of the child. It is up to the parents with the help of the doctor to ascertain that these surgical operations are performed in the interest of the person with Down syndrome and in keeping with beneficence.

As regard purely aesthetic operations, not involving functionality, the members of the family generally put forward two motivating factors. The first is to cancel or reduce as far as possible the evidence of diversity present on the body, and the second to reduce the social stigma and avoid possible reactions of rejection, especially in those social contexts where the culture of integration is less developed.

There are numerous studies that have shown how it is difficult to achieve any benefit to the person with Down syndrome through these operations and that frequently there is the possibility of causing the opposite effect: the aesthetic somatic change can determine in the minor a sense of alterity to his own image (hindering the process of self-identification) and the perception of being rejected by the social environment and especially by those who should take care of him. Moreover there is the risk of increasing the illusion, for family members, that aesthetic surgery modifies the condition of disability.

The Committee believes that acceptance of disability should not take place through modification of the external body, but through recognition of the person, which is expressed in the relationship and acceptance of his existential condition.

Therefore the NBC sees no ethical reasons to justify those with Down syndrome being treated any differently from the provisions established regarding minors or the incapacitated, as being unable to exercise their own highly personal rights, they can not be subjected to medical treatments that are not necessary for health.

3. Reconstructive surgery

Reconstructive plastic surgery raises bioethical issues only partly comparable with those related to aesthetic surgery and as regards the retrieval of organs it falls within the context of deceased organ donation.

Recent developments in this field of medicine in various countries open the way for the 'reconstruction of the human body'. The main obstacle to the expansion of this type of transplant is represented by the anti-rejection therapies,

and therefore immunosuppressive.therapies. In the near future an effective treatment free or almost free of side effects should be attained (such as, in particular, the onset of tumors) capable of preventing the rejection of tissues that come from another human being, it would open up the technical possibility of reconstructing every part of the body. Currently, in addition to transplants of bone, muscle, vascular segments, skin, teeth, etc.., compound tissue transplants[7] are performed consisting of upper and lower limbs, fingers, feet, face, abdominal wall, larynx, and uterus.

In this context, the aesthetic and therapeutic components are closely related, but the latter prevails over the former. The primary aim of reconstructive surgery is the repair of a functional impairment caused by trauma, accident, illness, etc. or the correction of a congenital malformation. These are "non-life-saving transplants," that make their foundation of legitimacy the protection of physical integrity and health of the patient, in consideration also of the general quality of life (which also includes psycho-social aspects).

Some reconstructive surgeries are recently leaving the sphere of experimentation and pilot studies or attempted cures. Others still have an experimental character as insufficiently tested by experience, resulting in uncertainty about the possible positive or negative effects. The experimental dimension does not just consist in the technical execution of the operation, but also includes consideration of the side effects of the intervention. There is not yet a sufficiently high number of operations and adequate observation time of the follow-up (at least 10-15/20 years) to have reliable data on organ survival rates and on the implications for the patient. Among these there are included the transplants performed on the face, which can be small or large in extension (total or partial) and the transplantation of limbs. It is true that these kinds of reconstructive surgeries, in many cases, therefore, can be defined as *experimental treatment transplants,* they take place in situations where the disability suffered by the patient, is no longer physically and / or psychologically sustainable or otherwise curable[8], and as such this means that the operation represents the only valid and real hope for the health of the patient, understood as the possibility of reacquiring a relational, sentimental and professional life.

The NBC believes that such interventions, although not essential for the survival of the patient, are nevertheless ethically justifiable, albeit subject to an evaluation of the relationship between benefits and risks, also considering the possibility that the anti-rejection drugs and their long-term use (even lifelong) could compromise health or cause the formation of tumors. It must be said that in this

[7] Transplants are carried out to date in Italy, Spain, France, Austria, Belgium, Poland, United States, Canada, Malaysia. Recently, Australia, Brazil, Argentina, Lebanon, Turkey, New Zealand, China, Japan. The first hand transplant was performed in Italy by Prof. Marco Lanzetta Hospital San Gerardo Hospital in Monza in 2000. This was followed by two others, and a bilateral hand transplant performed in October 2010 by the team of Prof. Massimo Del Bene, the head physician, again at the San Gerardo Hospital in Monza.

[8] It 'should be kept in mind that by using sophisticated techniques of autotransplantation, important results can be obtained: it is possible to transfer to the face portions of skin, subcutaneous tissue and muscle from the abdomen or back and take it from undamaged areas, such as the back, large tissue grafts without the patient having to resort to anti-rejection therapy. Transplantation should be selected only when there are no alternative treatments that are less invasive and risky.

context, scientific research has recently made considerable progress, allowing early diagnosis of rejection in order to treat and prevent it[9], control side effects if not actually reducing or even eliminating them in certain cases[10], taking immunosuppressive drugs. In particular, in the case of external organ transplants, the receiver is generally a healthy person - in the physical sense of the term - (as opposed to those who receive an internal organ who live with their condition of illness), so they are better able to support and respond to treatment and side effects.

Nevertheless, health risks currently exist and the choice between them and the possible advantages of transplantation should be entrusted to the patient. The delicacy of the issues involved once again calls for particular attention to consent which assumes that the patient is given full information in order to enable the taking of a decision that is personal, free, and conscious and objectively in the patient's exclusive interest. The consent, with the information to be given, obliges the doctor, even more than is usually the case for indisputably necessary operations, to draw attention to the complexity and delicacy of the surgery and thus highlight the uncertainties of the results and risks associated with the side effects of treatment after surgery, even faced with a performance according to *leges artis*. For this purpose it is essential to provide a specific consultation, involving physicians, psychologists, psychiatrists, physiotherapists. The consultation should take place well in advance of the surgery, have wide margins of time and continue as long as possible even after surgery. The consultation would also involve family members, called on to participate and support the person in the decision. Furthermore, it would also be opportune to draw the attention of the patient even to the consequences that the operation may have in other spheres, especially work (the possible discontinuance or modification of a privileged position for the disabled) and insurance (changing insurance contracts for health due to the risks of drug therapies after surgery). It is also hoped that implementation of appropriate informed consent will also make use of new information technologies, facilitating the collection of information and knowledge through access to sites accredited by competent government institutions as well as national and international registries where the latest studies in this sector are published and where publications generated by scientific studies can be found.

As regards the regulatory aspect, reconstructive transplants generally fall within the context of the regulations governing the removal and transplants of organs and tissues[11]. And in fact, in several European countries (e.g. In France, Spain and even Italy), multi -tissue transplantation (hand, upper limb, lower limb, foot, face) is considered equivalent to an organ transplant. This is based on consideration of several factors: the exacting surgical commitment, the objective difficulty in finding the donor; the impossibility of preserving the tissue and the

[9] As regards, in particular, the hand transplant, the visibility of the organ allows immediate diagnosis (compared with internal organs). In addition, the simultaneous transplantation of a piece of skin positioned at hip level allows anticipation of rejection in order to treat it before it even occurs.

[10] Currently under experimentation is transplantation, with organ, of bone marrow which, by producing cells not in competition with the original cells, helps to prevent rejection.

[11] In our country the legal regulation is given by Law No. 91/1999 (*Provisions for the removal and transplantation of organs and tissues*).

objective necessity of using the organ transplantation network for the donation transplantation event; the need to monitor the follow-up of the receiver.

However, unlike the more usual transplants (kidney, liver, heart, etc.), there are some specific difficulties in the procurement of organs and tissues. The fact that this transplantation is not for life-saving purposes but for therapeutic intervention, in many respects still partly experimental today, may alter the therapeutic alliance with donors. They and their families may be less favourably disposed to a destination that is not decisive for the life of the recipient, even in consideration of the therapeutic nature of the operation and the not always reliable results. Also not to be underestimated is that there may be a lack of willingness to donate part of the face and limbs, both because this alters the appearance of the cadaver, and for the symbolic, identitary and relational significance which they have. Especially in face transplants, the fear may also arise - under discussion on a scientific level - that the recipient could acquire the somatic resemblance and certain forms of expression of the donor. This means in terms of consent that these situations are regarded as "exceptional cases" and call for a selective and personalised request to the families of the donors. And this, notwithstanding that, at present, the law keeps silent on this point: there is no provision for "partial consent/dissent" and donors are multi-organ donors.

It must be added that for this type of transplant there is the difficulty of finding compatible donors since the problem is not only the genetic similarity but also external appearance (donor age, colour, skin texture, size). Just as a further obstacle to cadaveric donation may come from the prohibition present in some legislations, like our own, of designation to individual beneficiaries with whom the donor could be linked by family or emotional ties. This is a precondition for living organ donation. And even though there is here no condition of urgency, the analogy with such a donation seems to offer support to this choice, as well as the principle of beneficence, which does not preclude the provision of privilege to the people who are with us in a special relationship and for whom we have a particular responsibility.

Finally, alongside the scarcity of available organs there is a further problem, related to the selection of recipients. Since resources are scarce, the selection must be made on medical grounds, both privileging the bearers of deep and irretrievable lesions with significant functional deficits (such as an absence of both hands or legs, the impossibility to take food, trouble breathing, the disfigurement of the face, etc.), as well as by evaluating the patient's ability to bear and endure the potential consequences, not only physical, but even psychological of the operation.

All these difficulties - which have a negative effect on reconstructive surgery - require more public awareness campaigns for the donation of external organs and tissues, as typically takes place in the donation of internal ones.

4. Recommendations

A) With regard to aesthetic surgery

1. Being a strictly non-therapeutical intervention, the NBC reiterates the deontological criteria governing medical practice, sometimes-disregarded in this specific field-in favor of compliance with the request expressed by individuals, and emphasises the unacceptability of disproportionate intervention, as it is overly intrusive or unnecessarily risky and inappropriate in relation to the possible benefits requested by the patient or that become a sort of 'aesthetic persistence` or mere exploitation of the body.

2. Moreover. the NBC believes that the licitness of the intervention should be subject to certain conditions and priorities, set out below:

- the balancing of risks and benefits should be commensurate with the psychological and physical conditions of the patient, with regard also to the perception that the patient has of his own body and the results expected from surgery;
- the functionality of the organs concerned must take priority over the aesthetic result;
- the information given to the patient must be complete, with adequate counselling, including psychological counselling, and clear and comprehensive reference to the psycho-physical complications, the limits of practicability of the surgery and the possibility that the patient's expectations may not be completely met.

3. The NBC believes that there are general limits on the licitness of purely aesthetic operations on minors and people unable to give consent, unless these interventions are not in their sole objective interest in terms of health and psychological balance during adolescence.

The protection of minors should also be guaranteed by banning advertising and television broadcasts which lead to the rejection of self-image.

Those working in this sector should be informed and made aware of the responsibility regarding the risks their messages can transmit.

In particular, the NBC does not consider legitimate aesthetic surgery on children or incapacitated adults with Down syndrome, aimed at the conformity to social canons of 'normality', especially if it is invasive and painful.

4. The NBC believes in promoting appropriate social information and education as to the risks and benefits of aesthetic surgery. It calls for a critical awareness of the importance that the decision to undergo these operations must be both independent and responsible, taking into account the influence that can be exerted by undue external pressures, including today's consumer and media culture allied with the increasingly pervasive business of beauty and fitness.

5. The NBC hopes for greater rigour in the training and professionalism of the aesthetic surgeon, also aimed at achieving an understanding of the psychological and ethical aspects related to this specific medical practice.

In this context there should be promotion of professional *guidelines* that reiterate this specific responsibility.

B) With regard to reconstructive surgery, with particular reference to the most invasive transplants (e.g. limbs and face)

The NBC recommends the following.

1. Although not essential for the survival of the patient and though still - in some respects and in some areas - therapeutically experimental, these interventions are ethically justifiable, subject to a careful evaluation of the risks and benefits, relatable to a general consideration of the improvement of the quality of life of the patient.

2. Appropriate counselling is required in advance of the operation and which lasts in time (extended even to the family), due to the complex issues that involve risks and benefits, accompanied by a constant psychological monitoring of the recipient. The follow-up is essential, not only for the patient, but also to acquire useful data for the development of future medical technologies.

The patient should be informed accurately and comprehensively of the risks for health and the severity of the anti-rejection therapies and the fact that in any case they lead to a dependency on these drugs (with possible negative outcomes) which could even last a lifetime.

3. It is hoped that in the implementation of appropriate informed consent there will be use of new information technologies, promoting the collection of information and knowledge through access to sites accredited by government institutions, as well as national and international registries where the latest studies in this sector are published and where scientific publications generated by the study can be found.

4. Awareness raising campaigns are recommended for the donation of external organs and tissues, as typically takes place for the donation of the internal ones.

In this context, the possibility of an integration of the legislation providing for "partial" consent or dissent to external organ donation is also hoped for.