

Functional neurosurgery for severe psychiatric disorders

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Introduction

On June 12, 2001, the National Consultative Ethics Committee received a referral concerning the ethical implications of practising functional neurosurgery, which is an experimental process for the treatment of severe psychiatric disorders, from M. Bertrand, Chairman of the Departmental Commission for Psychiatric Hospitalisation in the Haut-Rhin.

The question concerns the case of a 20 year old patient, suffering from severe psychiatric disorders (agitation, hetero-aggressivity, threatened self-mutilation) for which he had been hospitalised almost continuously since 1995. Since his condition is proving refractory to the usual psychiatric medication, surgical procedures are being considered so as to try and reduce his potential for violence and make him less dangerous to others. The health caring team hopes in this way to be able to provide more humane treatment than the almost prison-like incarceration which is his present lot.

More specifically, the request for an opinion concerned :

- The very principle of recourse to functional neurosurgery (psychosurgery) for severe psychiatric disorders ;
- The methodology of such recourse and the protective measures to be adopted,

This applies in particular because although, in rare cases, functional neurosurgery does seem to be both necessary and useful, the fact that it is in principle irreversible raises, more than for any other treatment, the major issue of prior consultation.

In parallel, and for another pathology (treatment for abnormal movement such as is observed in severe cases of Parkinson's disease), Professor Benabid, Unité Inserm U318, Pre-clinical neurosciences, Grenoble teaching hospital, also referred to the CCNE on October 17, 2001, on the subject of ethical implications in connection with new methods for high frequency cerebral stimulation. With these new methods it is possible to mimic the effects of "conventional" functional neurosurgery, but in a way which is potentially reversible and adaptable, so that the many undesirable side effects of lesional surgery could be avoided. Progress in neurobiology and functional cerebral imagery provide hopes for a better understanding of the neuronal processes involved in certain severe mental disorders. Several medical teams in various countries are exploring this promising avenue of research. They hypothesise that *"should these new and less aggressive methods for cerebral stimulation lead to reconsidering with optimism the possibility of developing reasoned,*

scientific, and prospective psychosurgery", a review of the aims and indications of functional neurosurgery should be seen as inevitable, and all the more so because these methods seem relatively easy and more recently, benign.

However, according to Prof. Benabid, this could only be conceivable after an evaluation of the possible ethical implications which would, without a doubt, be raised. In the past, strong (and justified) criticism had been expressed concerned the initially *"uncertain and difficult-to-reproduce nature of results"*, to which was associated *"a deplorable lack of precision regarding indications, so that ultimately the procedures were practised with neither restraint nor discernment, and with no regard for the fundamental rules of ethics"*. It is in this context which is still encumbered by the passions of medical history that the issue of a possible revival of the practice of functional neurosurgery arises.

I Historical perspective

Psychosurgery has a long and controversial history, in which medical, moral, social, and political considerations intermingle. Defined as a surgical ablation or destruction of nerve transmission pathways with the aim of modifying behaviour, this functional surgery has now evolved (with the progress of new methods of medical imagery or of neurobiology) into a less invasive and more selective technique than the conventional "lobotomy" of the 40s and 50s.

After being initially described in 1936, this surgical procedure flourished, and was used not only for patients confined to psychiatric institutions. Indications became excessive. There was a strong desire to relieve over-population and under-medicalisation in certain asylums and hospitals, so that lobotomy came to be seen as a means of calming down and even sending back home an appreciable proportion of committed patients¹. Economic considerations were not foreign to these developments, without too much attention being paid to selection and consent on the part of patients. This unrestrained development of lobotomy explains why it is so difficult to gain an objective evaluation of its true efficacy.

Starting in the 50s, when neuroleptics and chlorpromazine were discovered, increasingly sharp criticism of psychosurgery was voiced. Pharmacological progress led rapidly to a decline of psychosurgery, although it never disappeared altogether and continued to be used in cases viewed as otherwise refractory to treatment. In parallel, the fears aroused by this irreversible and mutilating cerebral surgery, State controlled, causing a modification of behaviour, led to increasing concern on the part of public opinion, highly amplified by the media. Following spirited social controversy, in the United States, a Federal commission was convened in 1977. Their conclusions were surprising, and they submitted a favourable report which discredited allegations claiming that psychosurgery was used to control minorities, restrict individual rights, or that its undesirable effects were non ethical. The Chairman of National Committee for the Protection of Human Subjects of Biomedical and Behavioral Research, even went so far as to declare: "We have looked at the data and they did not support our prejudices. I, for one, did not expect to come out in favor of psychosurgery. But we saw that some very sick people had been helped by it... The operation should not be banned"².

These historical considerations explain why legislation was passed in numerous countries leading to its prohibition in a number of American States and other countries such as Germany or Japan. It continues to be performed, but is strictly regulated and controlled in a few American centres, or in Finland, Sweden, the United Kingdom, Spain, India, Belgium, and the Netherlands³. In France, an IGAS² report listed 32 lobotomies performed on 30 patients between 1980 and 1986 (a study of 7 neurosurgical units out of a total of 72 French centres). The French figures for 2001 are not known. Elsewhere, about fifteen cases a year are reported for the U.K., seventy in Belgium, and approximately fifteen for the single case of the Massachusetts General Hospital in Boston (one of the American reference centres).

These controversies concerning psychosurgery seem to summarise the history of medical thinking in the XXth Century. Locating human thought in the cerebrum, and the revolution brought about by Pasteur led to disengagement from the multifactorial and "magical" concept of disease. The neurosciences have benefited from the "anatomy-clinical" approach, while the prodigious discoveries in psychoanalysis opened further horizons. The ethical implications of medical practice have become more formalised. Perusing today the fundamental principles stated in the Nuremberg Code of 1948 (mandatory consent, need for research, prohibition of any unnecessary pain or physical or mental injury, value of humanitarian values, scientific ethics, and protection of individual liberty of the subject), the degree to which they conflict with the practice of psychosurgery becomes obvious.

In fact, after immense initial hopes (which were materialised by the disputed award of the Nobel Prize to Egas Moniz in 1949⁵), extensive proliferation, indiscriminate application and excessive broadening of indications⁶ led to categorical condemnation and quasi cessation of psychosurgery. Its history may be interpreted as a paradigm of human ethical concepts, oscillating between two extremes. Although the lobotomy of the 50s (imprecise, complicated, jumbled indications) is a thing of the past, results obtained in the treatment of Parkinson's disease by neurostimulation (guided by the advances of functional cerebral imagery) have totally transformed the situation and seem to have opened up a new avenue. In the circumstances, the whole issue must be restated for patients suffering from obsessive-compulsive disorders (OCD) - can treatment of "psychic" tremors be considered in the same light as the treatment of Parkinsonian muscular tremors? Can patients suffering from "purely" psychiatric conditions be transferred to the organic territory of cerebral pathologies?

II The various techniques and their effects

1. Conventional "lobotomy"

The techniques initially proposed (prefrontal leucotomy - or "standard" prefrontal lobotomy - and transorbital leucotomy) aimed to destroy part of the frontal lobes or their connections to the limbic system because of the role played by these structures in cognitive and affective functions⁷. Personality changes brought about by the early destructive techniques were frequent and often deplorable with the appearance of a significant "frontal lobe" syndrome, characterised by permanent apathy or euphoria, inconsistency, puerility, boorishness, impaired judgement, and chaotic behaviour⁸. Added to these effects directly related to the mutilation of cerebral tissue, potential harmful side effects occurred such as epileptic seizures or aggressivity.. The violence of this "treatment", is one of the reasons why it was ultimately condemned unanimously, summed up as follows : *"the lessons of a recent past when psychosurgery resorted to three subterfuges: firstly, experimentation camouflaging as therapy; secondly, in countries where vigilance is lax, i.e. the third world, Asia in this case, trials producing advantages for the sole benefit of the privileged classes; and thirdly using public order as an alibi for performing exeresis on violent subjects⁹".*

2. Functional neurosurgery

Since the 60s, these early damaging techniques were abandoned in favour of much more limited surgical procedures compared to the conventional lobotomy, although they are still destructive. Grouped under the heading of "psychosurgery", they refer to procedures based on a "functional" neurosurgical approach. Techniques still applied are :

- anterior capsulotomy, which interrupts frontothalamic connections in the internal capsule

- cingulotomy : the partial destruction of the cingulate gyrus, whereby the affective impact of symptoms can be attenuated by altering certain connections within the limbic system. More recently, an MRI-guided stereotactic procedure has been developed.
- subcaudate tractotomy, an intervention on the lower portion of the frontal cortex aiming to destroy the fibres which connect it to the hypothalamus and the head of the caudate nucleus.
- bilimbic leucotomy, which combines cingulotomy and subcaudate tractotomy.

Unlike conventional "spatial" surgery, this is in fact a new "symptomatic" surgical therapy which corrects functional manifestations and not the structure of the individual. As is the case for any functional surgery, practitioners are even more prudent in the formulation of indications than they are for "conventional" surgery, and insist on the absolute necessity for meticulous evaluation of patients, in a demanding multidisciplinary framework.

The results (evaluated on the basis of short series because of the paucity of acceptable indications) are generally considered to be effective despite the extreme severity of the symptoms of patients willing to undergo these procedures. The severe cognitive behavioural disorders, with marked apathy and indifference, which were experienced by early lobotomy patients, are no longer observed. An evaluation of the results of these new techniques is reinforced by more scientifically based analysis, measuring post-operative developments with objective scoring systems. The undesirable effects, which were the object of exhaustive reports because of the poor reputation attached to these interventions and the repugnance they arouse, do not include any specific morbidity. The insufficient results associated with the early work of inexperienced teams are due to the "initial failure" of a surgical act which was voluntarily "cautious" and of limited amplitude, so that because of too restricted lesioning, the outcome was simply a moderation of the symptoms. These findings sometimes led to revision surgery before new sets of patients were able to benefit from immediate single interventions replacing the previously cautious two step procedures.

More recently, the administration (guided by modern cerebral imagery techniques) of a highly focused gamma radiation ("gamma-knife") produced clinical results similar to these new neurosurgical techniques, except that it is minimally invasive.

3. Cerebral stimulation techniques

Besides the development of these recent surgical procedures which, by their very nature still involved some degree of mutilation, new hopes are now arising with the appearance of some very different - because they are non-destructive - fresh techniques based on stereotactic neurostimulation. Outcomes are still being evaluated, but the techniques have already been used for other indications such as severe Parkinson's disease, and were found to be almost free of any complications. There is no permanent cerebral damage. Clinical research efforts are ongoing with the hope of gaining, with the help of advanced cerebral imagery techniques, better identification of the pathological areas, and therefore of locating ever more limited "intracerebral targets".

These psycho-electro-physiological techniques seek to achieve psychomodulation by implanting into the cerebral parenchyma, stimulating electrodes in specific locations such as the anterior limb of the internal capsule. The equivalent of anterior capsulotomy can be achieved, in what should be a reversible manner, by the induction of a radiofrequency current. It is hoped that this recent research will lead to reversible procedures. The techniques are similar to those which have proved effective in the treatment of severe Parkinsonism. In this particular indication, the strictly symptomatic nature of the treatment is demonstrated by the reappearance of clinical symptoms when stimulation ceases. Scientific follow-up of this category of patients has also shown that certain affective manifestations may be accessible to such neurostimulation.

Although therapeutic hopes based on the preliminary outcome of neurostimulation techniques (and their initial results in severe Parkinson's disease) seem promising, in theory, the promise of reversibility is still an issue. Apart from the possibility of reduced efficacy or relapses if treatment is too mild, there could also be a risk of "paradoxical" complications, or even harmful effects such as suicidal inclinations in patients who, having once been stimulated, regain lucidity regarding their past condition and are unable to accept it.

Although they are very different from surgery mutilating the cerebral parenchyma, psychologically and socially these stimulation techniques will always remain less acceptable than for instance cardiac stimulation. However, the voluntary nature of the patient's action in submitting to treatment remains: the patient is still free to intervene in the stimulation process (by interrupting it), and the fact that the electrodes need to be re-positioned at regular intervals is proof enough of repeated patient consent. In fact, these new methods of modifying cerebral functions share many points in common with the behavioural modifications induced by pharmaceutical treatment. In both cases, the aim is rather to modulate behaviour and conduct than to control the individual concerned. The theoretical risk (or fantasy) of subjection of the individual should be weighed against the will to liberate the patient from the true subjection inflicted by the disease...

III Ethical issues

The present indications for psychosurgery, although exceptional, have not entirely disappeared¹⁰. Although the procedures still seem legitimate, physicians tend to forgo the use of this tool, because of ethical alarm at its lack of codification. Without seeking to minimise the considerable difficulties encountered in obtaining patient consent, the essential issue is certainly the "ethical approach" of psychosurgery. Our apprehensions, risks, and certainties thus come to the forefront and the ethical legitimacy of such reflection is undeniable.

The ethical approach of the issue of psychosurgery cannot sidestep the epistemological study of the fears and fantasies associated with any intervention on the brain, in other words, the risk of more or less irreversible modifications to the psyche by external means. Ethics cannot simply accept a response based solely on a scientific history which culminated in making any debate on the subject unacceptable. On the contrary, ethics demand that, in the light of new techniques, the same questions should be asked again but in different terms. But new words are also coined to describe these treatments for a new population of patients, and these semantic developments finally resemble attempts to describe (or rather render less dramatic) the feelings of healthcare providers: lobotomy vanishes in favour of psychosurgery, which fades away and is replaced by functional neurosurgery, which now turns into "neuromodulation by cerebral stimulation"...

Treating by neurosurgical exeresis recognised organic disorders such as a brain tumour, raises no special ethical issue in clinical practice. Although this type of pathology may bring about a certain degree of mental confusion, the indication is generally selected by obtaining consent from the patient or the family. In contrast, one can well imagine that "much of the hesitation and obstruction that attend discussions of consent to psychosurgery are based upon unwillingness to view mental illness in the same way as physical illness"¹¹.

Integrating into the equation knowledge of favourable results gained by the use of intracerebral stimulation techniques for the treatment of severe Parkinson's disease, gives even sharper focus to the issue. As in this truly organic pathology, neurostimulation

techniques which mimic the effects of functional neurosurgery, have demonstrated promising results for patients troubled by severe obsessive-compulsive disorder (OCD). With such patients, who are very eager for "organic" correction of their disorder, perhaps some of our reluctance stems from the possibility (apart from the legitimate issue of consent) of extension to severe psychiatric disorders with self- or hetero-aggression tendencies, or on the contrary to over-simplification such as "should you cut the brain to save the mind"¹² ?

In 1996, the World Psychiatric Association approved a declaration the preamble of which read as follows : 1. Psychiatry is a medical discipline concerned with the provision of the best treatment for mental disorders; with the rehabilitation of individuals suffering from mental illness and with the promotion of mental health. Psychiatrists serve patients by providing the best therapy available consistent with accepted scientific knowledge and ethical principles. Psychiatrists should devise therapeutic interventions that are least restrictive to the freedom of the patient and seek advice in areas of their work about which they do not have primary expertise¹³.

These preliminary reflections demonstrate that ethical issues connected to this new technique come under three headings :

- the scientific validity of the technique and therefore of its evaluation; the patient's consent;
- the possibility of a conflict between the interests of the patient and that of society, in particular in the case of dangerous or violent individuals.

The central difficulty is therefore one of legitimacy, of the status of a new technique in the ethical approach of an issue for which the "ethical" response is purely technical. But in the same way as medically assisted reproduction has always generated new questions, there is no reason why psychosurgery cannot be serenely broached once more on the basis of new data.

There are in fact a list of questions to be answered :

- What is the potential indication for psychosurgery ?
- Is an evaluation of research activity being considered, or are these techniques already part of the therapeutic inventory ?
- How (and by whom) should the pertinence of these indications be evaluated ?
- Are we certain of the reversible or irreversible nature of certain interventions?
- Can the issue of a patient's consent be considered for patients who, in essence, have lost a greater or lesser portion of their freedom of judgement ?
- Where are the limits of informed consent in such a context ?
- To what extent should society exercise critical judgement ? What institution should take on the responsibility for such patients, and according to what standards ? What should be the State's role in such therapy ?
- how should society think for the mentally retarded ?
- How should quality of life be assessed, from the viewpoint of the subject, or that of society ?

1. Indications today

Specialist psychiatrists and neurosurgeons who were consulted, all agreed that the essential indication is first and foremost obsessive-compulsive disorder (OCD). In the throes of these disabling treatment-refractory obsessive psychoneuroses, patients are truly tormented by the painful awareness of their condition and their lives revolve entirely around their rituals. This would be the indication for which psychosurgery is the most frequently resorted to (a priori more than 70% of such interventions) and for which it is most successful with notable objective improvement. With this indication, the failure of treatment by medication makes consent almost irrelevant since patients are more than eager, and sometimes implore for help by this technique.

The other possible indications raise radically different problems, be it as regards pathology, frequency, ethical implications, or responsibility :

- Some severe depressions (chronic melancholia) refractory to massive treatment (i.e. at least 2 courses of antidepressant chemotherapy comprising several antidepressants and several courses of somotherapy);
- Several affective disorders, such as the major treatment-refractory schizophrenic psychoses;
- Finally, some cases of aggressivity to oneself or to others, which are all individual cases.

2. The relationship between therapy and research procedures

In practical terms, pre-surgical evaluation enabling a medical selection of patients applies solely to patients suffering from OCD. Objective criteria can be arrived at on the basis of a strict multidisciplinary approach. For this indication, the following criteria have been selected¹⁴: a) diagnostic criteria established for at least five years, b) significant suffering evidenced by validated clinical and social function scores, c) recognition that the usual medications, used either singly or in combination for at least five years, have had no effect or had to be stopped because of intolerable side effects, d) appropriate treatment of an associated co-morbid disorder, e) a poor prognosis for the disorder in question.

In all cases, it would be necessary to :

- Verify that the global management of the individual is correctly evaluated.
- Establish "pharmaceutical deficiency".
- Document the potential benefit using objective instruments (scales) together with an inter-institutional evaluation.
- Request the opinions of multiple psychiatric teams (including the opinion of at least two other psychiatrists).
- Obtain patient consent. The family cannot be asked to give consent, which must be given personally. Obtaining consent does raise some particular issues with OCD, because it is part of an individual - almost contractual - action, since this therapeutic option seems to be a last resort.
- Inform the patient of the risks, and prefer the less intrusive stereotactic techniques.
- Propose a national procedures registry (to facilitate evaluation).

For other indications, the scientific demand for research to be pertinent is even stronger, possibly dominant, in view of the uncertainties veiling the pathology and its presumed treatment. Although a degree of tension emerges whenever irreversible cerebral manipulation is considered, obviously the reversibility of new techniques can only be formally established by encouraging research on the subject ! It therefore seems ethically improper to oppose a project which precisely aims to guarantee reversibility of the effects produced. In a previous CCNE report on the subject of consent¹⁵, the point had already been made that *"The intricacy of the care and research relationship has become a major characteristic of 'scientific medicine'. This should be a subject of pride. When it engages in research, medicine questions its own principles, corrects its mistakes, and progresses. Good research is not sufficient in itself to ensure quality health care, but it does contribute"*.

3. Consent

The concept of consent may take on very different meanings depending on whether the approach is medical, legal, philosophical, or ethical¹⁶, whether it only concerns the individual in question¹⁷, or whether it is given for the benefit of a third party¹⁸. Beyond the general implications of the concept of consent (which CCNE has already referred to frequently), this remains a crucial issue in psychiatry, more than for any other medical discipline, and particularly so when psychosurgery is one of the options.

There again, patients suffering from OCD must be considered apart from those affected by other psychiatric ailments, some of which involve violence (and/or involving diminished judgement) and for which there has not been conclusive evidence of efficacious benefit from medical treatment.

With severe obsessive psychoses, consent appears in the same light as for any other medical discipline. Patients are not unable to exercise judgement, and since they are fully conscious of the torment they truly endure, they are the first to call for the intervention. This sometimes strong or even demanding claim in fact gives singularity to the notion of consent in this pathology; it may in fact be closer to desire than to a statement of consent *stricto sensu*. In the presence of this desire, physicians sometimes need to recognise the anguish created by the pathology, and to consent to this request...

The "last resort" nature of psychosurgery nevertheless forces the healthcaring team (leaving aside the issue of consent) to consider possible medical objections :

- *"Have the diagnosis and evolution of the condition been known, with sufficient probability, for a sufficient length of time, after having tried all appropriate therapy, to justify psychosurgery ?*
- *Are the indications, the type of intervention, and its outcome known with sufficient precision ? Are the causes of failure or success correctly evaluated, for a sufficient number of patients suffering from the same condition ? (...)*
- *Would it not be preferable - remembering the implications of the discovery of neuroleptics - to await new advances in pharmacology or neurochemistry, rather than commit the patient to a surgical process leading to irreversible effects¹⁹?"*

Thus it is that sensitivity to the reality and intensity of the patient's distress brings the conviction that it "almost non-ethical" to deny such treatment to patients suffering from disabling, chronic, and intractable disease, and all the more so because the risk of social, somatic, and mental complications (including the risk of suicide) cannot be discounted. A legitimate ethical question is how long a patient should be left to suffer medical therapeutic failure before offering neurostimulation.

However, for patients suffering from aggressive delusional conditions (who may be dangerous for themselves or others), the question of consent is problematic. It would even be wishful thinking to imagine that the validity of consent ("free and informed") bears scrutiny in cases where judgement is severely impaired. Nevertheless, all efforts must be made to secure the patient's assent, even though this "consent" may be dubious in legal terms.

Be it in a healthcare situation or in biomedical research, pains should always be taken to do as much good (and as little harm) as possible, while respecting the freedom of decision of those one seeks to help. Even though duty calls for a constant effort to reconcile these two principles, there are cases of conflict. Following the ethical distinction between a "teleological" position, based on the principle of beneficence (or non-maleficence) and a "deontological" position based on the principle of respecting personal autonomy, in CCNE's Opinion n° 58, on consent²⁰, primacy is granted to the body's inviolability in contrast with positions adopted by other countries in favour of free decision. Against this background of French attitudes to consent, present trends on the subject of recourse to psychosurgery would constitute a form of exception which could not be justified by the medical profession alone.

The Code of Ethics of the medical profession in fact states that²¹ "*consent from the person under examination or care must always be sought*", and that "*when the patient is in a fit state to express his/her wishes, and rejects the investigation or treatment offered, the physician must respect that rejection, after having informed the patient of the consequences. If the patient is unable to express his/her wishes, the physician may not take action unless next of kin have been warned or informed, unless that is an impossibility or urgent action is required.*" Therefore, the issue of "being or not being fit to express a wish" is the crux of the matter. Further detailed instruction in the Code of Ethics on this difficult matter is unambiguous : "Consent from a mentally sick patient to treatment offered is most advisable and, if necessary, attempts to secure it may be insistent ; however, in case of refusal, the physician and the family must, in certain cases, ignore the patient's wishes. When mental aberration is clearly established, or if the patient is dangerous, commitment by certification or voluntarily to a mental hospital or institution becomes necessary. The law dated June 27, 1990²² on the commitment of the mentally ill, allows for the wishes of the patient to be ignored in certain cases, both as regards admission to a public hospital and administering treatment. When neurotic disorders or affective disturbances, even of a spectacular nature, do not alter the patient's personality nor prevent reasonable decision, no treatment may be applied without the patient's consent."

The transparency which is sought here must be weighed against the long-standing philosophical tradition in France which is opposed to such thinking. However, although pharmacological advances have been such that the indications for psychosurgery have almost vanished, in some very exceptional cases, the indication for neurostimulation seems to require further scrutiny. The issue, which touches on the confines of research and therapy, disturbs some of our traditional thoughts such as the distinction to be made between research with or without direct individual benefit, following the clear and academic separation between research in phase 1, 2, or 3... Although a research project which does not rest upon a properly conducted phase 1 is a scientific impossibility, there remains some ethical tension, since phase 1 research cannot be, by its very nature, therapeutic!

In view of these difficulties, response could be casuistic, based on a case by case discussion... In fact, the Madrid Declaration of the World Psychiatric Association states that "*Ethical behavior is based on the psychiatrist's individual sense of responsibility towards the patient and their judgement in determining what is correct and appropriate conduct. External standards and influences such as professional codes of conduct, the study of ethics, or the rule of law by themselves will not guarantee the ethical practice of medicine*²³" .

In the absence of consensus among psychiatric or neurosurgical associations, several initiatives are now being undertaken. However, the profession is clear that there is an

essential need to consult specific Committees to draft rules (such as the involvement of medical or non medical personnel capable of evaluating the handicap and the distress of family and intimates) . Nursing staff in hospitals might well be the link between the public and the doctors, because they can observe and assess the torment endured by patients.

In practical terms, and although such a method is alien to the philosophical tradition of our country, there could be the creation of a formal Committee tasked with establishing decision-making procedures for the purpose of providing succour, and also protection, to such patients. In the presence of severe psychotic conditions, rather than "*accepting a stopgap solution, i.e. surrogate consent, which is the result of deliberation between the attending physician, the expert, and the family or legal representative*"²⁴, a committee composed of the above, plus pluridisciplinary medical, and non medical personnel, together with individuals capable of evaluating a handicap, and the misery endured by the patient, the family, and the entourage, would help to attenuate the pain and anxiety of taking such decisions.

3. What does the notion "quality of life" embody ?

Connecting "quality of life and psychosurgery" arouses alarm. Identifying the whole of a patient's welfare with only biomedical welfare is an imposition with, inter alia, as a consequence, turning the patient into a victim of some "medical obligation"; the medical world cannot imagine how individuals perceive their own welfare. It may be tempting to consider that a patient who is no longer a threat to himself or to others, or whose behaviour is no longer exceptionable, enjoys a more acceptable quality of life than before the intervention. As regards the life of the psyche, quality of life may be viewed as inaccessible to medical, or even human, judgement. In fact, the symbolic value of symptoms, the cultural significance of the disease, personal and interpersonal significance, are always extremely complex. However, the emotional tangle which escorts psychic disorders must not lead to giving credibility to approximate media information based more on franckensteinian myths than on dispassionate scientific observation. Understanding another individual's experience of life is still fraught with disillusion, whereas to be attentive to suffering and attempt to alleviate it by any available therapy can be entirely justifiable.

5. How do the mentally retarded fit into our society ?

CCNE has repeatedly spoken in favour of society's duty of solidarity to those of its members who are most weak and deprived, but there is probably even more cause with mental retardation. However, our duty of solidarity must not obscure the reality of a possible conflict of interests between society and an individual, and the special protection that society must give to those who are vulnerable. If an individual is dangerous, the threat to society and incarceration must be put in the balance. The issue of hetero-aggressivity is the most troublesome because it leads to isolating or even incarcerating the person concerned. It is not good enough to present the problem as a binary choice between "detention" and "functional neurosurgery", nor to reintroduce the practice of forceful administration of treatment (even marginally), for fear of regressing by fifty years and accepting a surgical straitjacket instead of a chemical one. Finally, rather than distinguish between self mutilation and aggression against others, efforts should be made to find ways of protecting - not punishing - the patient and those in contact with him.

6. Is it possible to have an effect on human behaviour ?

It is clear that this question must be asked, even though it is equally clear that such practices are widespread. The development of psychotropic drugs (used not just to "calm" wildly agitated patients in an emergency..), the rehabilitation of sismotherapy (which is a new name for a now well defined and controlled medical procedure, performed in specialised units under general anaesthesia, thus banishing the memory of the "electric shocks" of the past) has accustomed us to a less passionate and dramatic view of the once sulphurous asylum for the insane.

With the progress of human development, scientific advances often bring to the surface of collective thinking, legal, political, or even moral issues. The troubled and controversial history of functional neurosurgery has made it impossible to review the scientific problem before due consideration has been given to the moral, social, and political aspects, to be then extended to medical and legal issues, and financial ones. Whatever may be the actual practical applications of these considerations, the fear that conduct may be controlled by such techniques remains (with no distinction made here between functional neurosurgery and neurostimulation, since this is surgery for the psyche..). However, an examination of the facts leads to questions on the quality of this risk of control: are we controlling behaviour or controlling people ? What is the relationship between an individual's thoughts and his behaviour ?

Modern neurology has taught us to view the human brain in the form of three structures becoming increasingly complex with the process of evolution. There is a "central structure", or "reptilian" brain which terminates the brain stem, a paleocortex containing the limbic system which is itself surrounded by the neocortex which is the seat of elaborate human emotions and behaviours. Steering clear of the risk of being overly influenced by a purely neurobiological vision of behaviour, a distinction must be made between what relates to the person, and that which relates to the personality. In a utilitarian view, psychiatry can be seen as a means of liberating a patient from the bondage imposed by his condition. But the fear remains of seeing a person dominated by personality, or of the possibility of overturning the concept of a person's responsibility for his actions. Far from applying a sharp separation between person and personality, the advances of functional neurology lead to reviewing (for oneself and for others) the question of safeguarding freedom of decision and the determinism of human action which will be the subject of a forthcoming CCNE Opinion.

7. Recent changes in the law and their legal consequences

Psychiatry is "uncomfortably wedged between the territories of law and medicine, between coercion and care²⁵". Thus, two of the considerations of a text of the Parliamentary Assembly of the Council of Europe regarding the situation of the mentally ill are an illustration of this discomfort : "....."Convinced that the concept of the criminally insane implies a contradiction in terms in that an insane person cannot be considered responsible for criminal actions; (...) Believing that abnormalities of behaviour in the province of morals or the law do not by themselves constitute mental disturbance²⁶".

In France, recent modifications to legislation highlight changes in the way in which such patients are viewed.

- The Conseil d'Etat published a ruling on October 26, 2001 which reinforces the physician's obligation to follow his patient's wishes, albeit at the expense of his own obligation to dispense care ; this dilemma needs to be solved on a case by case basis because of the impossibility of setting an intangible general rule.
- The 1993 revision of the Code Pénal (Criminal Code) revised the rules for criminal irresponsibility. Article 64 stated : "*there is neither crime nor misdemeanour when the offender was of unsound mind when the acts were committed*". It now reads : "*a person, who at the time the acts were committed, was suffering from psychic or neuropsychic disturbances which abolished discernment or capacity to control action, is not held responsible in law for those acts*". However, such a person "can be punished" if discernment has only been "altered" but not abolished. This distinction therefore broadens the space before "the frontier separating responsible behaviour from alienating neuroses and psychoses, based in some instances more on philosophical concepts - such as "free will" - or on moral ones - such as the perception of good and evil - than on strictly medical definitions²⁷". Recognising that judging the degree of legal responsibility or irresponsibility of persons suffering from mental illness is a difficult process, leads to an inevitable parallel with the difficult

assessment on the part of society to determine for these persons their capacity to be fully aware of their actions and consent to treatment. The difficulty of medical appreciation of the competence of such patients is reflected in the "bafflement of society when trying to judge the criminally insane"²⁸...

8. Is there any possibility of an institutional solution ?

There could not be any development, however limited, of such techniques, without some form of official examination of the soundness of the indications. One of the recent proposals made by a working group of the Steering Committee on Bioethics of the Council of Europe (initially published for public consultation, with a view to producing guidelines), stated the following on the subject of psychosurgery : *"where States continue to sanction the use of it, the consent of the patient should be an absolute prerequisite for its use. Furthermore, the decision to use psychosurgery should in every case be confirmed by a committee which is not exclusively composed of psychiatric experts"*²⁹ .

The existence of such committees, which already operate in some countries, Belgium for example, whatever the guarantees stipulated for their organisation and their function, be they decisional or consultative, will never eliminate all the ethical issues in this field. Such committees are not part of French medical tradition which favours the concept of a singular dialogue ; nevertheless, the multiple actors and the vast ethical fields which the management of such patients open, demand a decision on the issue of political responsibility, which would best be settled by a totally independent committee. In view of the special and exceptional nature of these pathologies and of their therapeutic indications, the type of committee proposed cannot simply cover the same ground as the CCPPRBs as they are presently organised. Whilst approving the spirit, the achievements, and the worth of these bodies, it does seem necessary to provide a new definition and a special operating mode³⁰.

The proposed committee would make individual assessments on a case by case basis and should be able to ensure multiple complementarities. It would guarantee the scientific rigour of indications, and also should ensure that the joint decision of medical (and non medical) participants in the discussion be taken with due regard for all appropriate points, including the human dimension. This body could be specific to France, for a limited number of approved centres (three for example). It would be stratified into two sub-committees which would be referred to in succession by the healthcarers in charge of the patient, to first investigate and then decide :

- **an investigating sub-committee**, composed of the French medical teams (each of which would be by nature multidisciplinary) who would be authorised to use these techniques and to determine the therapeutic indications. There should be ample room on this sub-committee for the presence of scientific specialists, and in particular, international specialists, whose expertise is essential. Their presence would be evidence of a clearly stated will for independence, and would also guarantee the pertinence and quality of the research activity.
- once the scientific and technical opinion of the previous body had been arrived at, the same committee, extended to include individuals qualified to deal with ethical problems, would become the **decisional sub-committee** composed to also include distinguished representatives of civil society³¹, and would consider the method used to obtain consent.
- Irrespective of the detailed composition of this body, care would need to be taken to achieve balance and complementarity so that compassion and human kindness preside over the decision. Because of the very singular nature of the problem it is essential to invent a new way of proceeding, so as to avoid both excessive scientific zeal or antagonism to science, and to allow society to play a role and express its opinion. Civil society must remain as an interface between the work of

this committee (which must achieve unanimity to take a decision, with a single unfavourable reply equivalent to a veto) and the practitioner, who will be the actor (and whose therapeutic responsibility remains unaltered). Civil society's role here is to discourage any medical complacency by constant questioning and delving into the further reaches of scientific and ethical beliefs.

Opinion

Many ethical issues are raised by the arrival of new techniques for neurostimulation. Advances in imagery, experience acquired in recent years through neurostimulation of neurological disorders, should be a source of encouragement for remedies which patients call for and which are performed by highly experienced medical teams. Prudence requires for these stimulation procedures, more so than for any other, that failures, side effects, parallel effects, be published; but this should also be the case for benefits and successes. For this purpose, strict protocols must be established, describing the scientific foundations and theories on which these therapies are based, and the prospective data to be acquired.

The emergence of new and promising cerebral neurostimulation techniques for treating certain ailments, such as Parkinson's disease, lead to considering their extension to other disorders, in particular psychiatric ones. Advances in imagery, the a priori reversible nature of these techniques, justify a re-examination of the technical problem of the surgical approach of "the brain" in the case of psychiatric disorder. This approach was brought to a standstill since the tragic history of destructive surgery, frontal surgery in particular, in the 50s.

A number of clinical observations have in fact shown the effectiveness of these new methods, in particular for obsessive-compulsive disorders (these disabling obsessional psychoses are a source of undeniable moral torment for patients whose lives are largely taken up by rituals). There is therefore justification for reviewing this therapy in a new light, and asking a certain number of questions.

Is this **research or therapy** ? Undeniably, it is both. And this dual dimension must constantly be present in the minds of medical teams. There is no such thing as phase 1 surgery whereby tolerance to a therapy can be tested before its effectiveness. However, the same spirit must prevail, that is controlled evaluation in a research environment for this therapeutic approach. Reversibility of results is essential.

The problem of consent. In this activity where both therapy and research are involved, consent takes on a new dimension, and a doctor must inform his patient of the consequences of the expected therapeutic effects, and also of the value of the research activity. Although it is clear that consent may be defective for patients suffering from psychiatric disorders, every effort must nevertheless be made to obtain that consent. In this way, even though a particular patient's "intervals of lucidity" may be very rare, they must still be sought persistently so as to be sure that the patient has been able to understand, perhaps very approximately in extreme cases, medical expectations and their consequences.

If neurostimulation is restricted to obsessive-compulsive disorders, consent will be all the easier to secure because some patients endure such suffering that they may be ready to accept, or for that matter demand, intrepid action. It is precisely this paradoxical ease of securing consent which could become dangerous in ethical terms, so that some degree of control is required. However, the patient must fully understand that in the initial phases of development of these techniques, research is an important component.

Every protocol must be approved by a special committee, according to criteria which must define : a) the conditions for selection of potential candidates, b) the validity of their consent, c) criteria as regards severity, chronicity, gravity, and failures of medical treatment, and d) mode of evaluation of results. Surgical teams will need to demonstrate their expertise and should it be less than extensive, to secure outside assistance by experienced surgeons. This single committee, guarantor of the scientific and ethical validity of indications, will have a dual task : instruction and decision. In view of new issues arising out of the emergence of **experimental therapy**, its task will also be to preserve the integrity of suffering human beings, and safeguard the respect of their autonomy, and of the objective help than can be given to them.

Economic efforts to reduce the cost of healthcare must not be the object, nor must judicial injunction be the cause. If the patient has given valid consent, and the therapeutic protocol is satisfactory, and the medical team has sufficient experience, can we consider that all ethical issues have been covered? This would not seem to be the case, because re-opening of indications cannot exclude abuse, and history in this respect is harsh and disquieting. To intervene on the brain for psychiatric reasons may be tempting for disorders focused on aggression directed at oneself or at others. **As soon as social or medico-legal judgement comes to the fore, it seems that surgical techniques should not at present be employed, and all the more so when cognitive disorders invalidate consent, and prevent the patient from making use advisedly of neuro-stimulation itself.**

In these circumstances, and in the present state of scientific advancement, the use of functional psychosurgery could be extended to include OCD as well as Parkinson's disease. Allowing it for treatment-refractory psychiatric disorders, in particular when self-aggression is present, could be considered, but it still seems a little premature. This extension should not include extremely severe psychiatric disorders with an element of **hetero-aggression**. Confronted with a mentally-disabled individual whose condition may lead to violence or inflicting it on others, society must carry out its duty of protecting particularly those who are vulnerable, but while doing so, must respect and protect the sick individual. For this purpose, reflection on the legitimacy of therapies which aim to modify behaviour cannot obscure the possible conflict of interest between society itself and a person suffering from grave personality disorders. Apart from the above mentioned scientific and technical developments, the principal issue will remain of whether it is possible, and if so in what circumstances, to modify the psychic identity of a person suffering from mental disorder. Although *"psychiatrists should devise therapeutic interventions that are least restrictive to the freedom of the patient"*³², and although priority should be given to non-definitive action, the ethical aspects are not entirely covered, and the most obvious of them is the value and validity of consent in a patient whose mental faculties of judgement are impaired.

To reflect on the possibility of intervention to **modify behaviour**, leads to questions on the possible, or even inevitable, **conflict of interest** between society itself and a person suffering from grave personality disorders. This relationship between society and a sufferer is in this case at its acme because intimates and society have their share of the patient's sufferings, and may seek surgical remedy without the patient's genuine consent.

In fact, **the degree of suffering involved in psychiatric disease may lead to calling for new approaches more than anything else to achieve a more humane quality of care than indifference in the face of incarceration, constraint, and degeneration.**

CCNE considers that the new cerebral neurostimulation techniques may be appropriate in a restricted set of psychiatric applications to some particularly disabling treatment-refractory pathologies, such as OCD. However, **because it is inextricably involved with research, some very specific concept of consent, validated by external appraisal, must be provided.**

The reversibility of the situation merits constant re-evaluation. Even though there is a guarantee of the non-definitive nature of the therapy, there may still be an ethical problem in that the patient may see himself as instrumentalised in his behaviour by the stimulation itself.

CCNE considers that other psychiatric conditions, even though they may comprise an important self- or hetero-aggressive element, in the present state of progress, cannot be accessible to either functional or neuro-stimulating psychosurgical intervention.

However, numerous issues are still pending :

- This is undeniably care, but it is still partly uncharted territory, and there is therefore an element of research, as was the case in early attempts to treat Parkinson's disease. Medical teams must always remember that this association with a degree of **experimental therapy** exists.
- Can an extension of indications exclude possibility of **abuse** ? History in this respect is harsh and disquieting. This is justification enough for restricting indications particularly, to begin with, to obsessive-compulsive disorders.
- Is there any call to speak of **manipulation**, i.e. action taken on the initiative of an external agent the result of which is modification of a person's behaviour? It is true that such manipulation is done for that person's benefit, but it is also done for the benefit a third party, and that benefit is problematic from the outset.
- Will it be possible to avoid **the subject of connection between the "I" and the "ego"** ? These connections, of the person, of the personality, to society are by their nature always difficult with a privileged vision of the **personality** (the "ego") by society to **the detriment of the person** (the inaccessible "I"). The notion of psychiatric suffering, only accessible to awareness with difficulty, can never be the subject of scientific evaluation to the same degree as an organic neurologic disorder such as Parkinson's disease. Leaving aside even its spiritual value, is it possible to reduce the explanation of mental function to the result of an intervention ?
- The notion of **psychiatric suffering and its factual inaccessibility** can never be the subject of scientific evaluation to the same degree as an organic neurologic disorder such as Parkinson's disease.

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