National Consultative Ethics Committee for Health and Life Sciences

Opinion N° 116

ETHICAL ISSUES ARISING OUT OF FUNCTIONAL NEUROIMAGING

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Introduction

In the same way as ethical issues began to arise in the mid-1970s with the upswing of molecular biology, today society as a whole is faced to an increasing extent with ethical issues arising out of the development of the neurosciences. They are generally referred to under the collective name of 'neuroethics'.

The term spans a vast territory. It includes clinical neuroethics, i.e. specific ethical problems raised by neurological and psychiatric disorders, but also the ethics of the practice of the neurosciences, in particular cognitive research, the ethical implications of progress in knowledge of the brain on our social, moral and philosophical attitudes, as well as the ethical issues raised by the current availability of possibilities of modifying the way in which the brain functions[1]. **The speed with which such imaging techniques are developing could lead to such practices gaining a degree of autonomy,** so that the connection with the sciences on the one hand, and with ethical reflection on the other, could become more tenuous.

Progress in the neurosciences has been totally dependent on advances in methods for exploring the brain, and among these, MRI holds a preponderant place in that it not only is the most used technique in clinical practice and for research, but it is also the most instructive as regards the structure and the workings of the brain. The profusion of accessible information it can provide is such that MRI is now an essential tool, for both clinical and research purposes, in the study of neurological disorders and, increasingly in the study of psychiatric disorders. It has radically modified the art of neurological diagnosis and is often also useful in making a prognosis and evaluating the efficacy of treatment.

This Opinion will be concerned only with ethical issues raised by progress in technologies for exploring the brain, in particular those which make it possible to study cerebral function, the archetype being, at this time, functional magnetic resonance imaging (fMRI).

Neuroimaging techniques, fMRI included, are also being used currently for purposes which have no connection to medical practice or research and, as such, raise a new set of ethical concerns. This is the case, for example, of the extension of its use, as given in the new law on bioethics of July 7, 2011[2].

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1 As far back as 1980, G.Canguilhem remarked on "the speed with which supposed knowledge of the brain's functioning is incorporated in intervention techniques, as though theoretical research was congenitally triggered by practical interests", in *Le cerveau et la pensée.* Published in: *G Canguilhem, philosophe, historien des sciences,* Albin Michel 1993, p.14.

2 Law on bioethics dated July 7, 2011. Art. 16-4: "Cerebral imaging techniques can only be used for medical or scientific research purposes, or in the context of forensic expertise. Express consent from the person concerned must be secured in writing before conducting the examination and the subject must be fully informed regarding the nature and purpose of the procedure. The consent statement will include the purpose of the procedure and may be withdrawn at any time without requiring any special procedure".

This Opinion will consider in turn:

- I) fMRI: technical approach and clinical research
- II) Ethical issues arising out of fMRI-based research
- III) Ethical issues arising out of the non medical use of fMRI
- IV) Confidentiality and data protection
- V) Several recommendations.

Annexes

1) The human nervous system
2) Methods for exploring the brain

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I. Functional MRI: technical approach and clinical research

I.1 Technical approach of functional MRI (fMRI)

With fMRI, the activation of certain areas of the brain can be seen as various motor, sensory, cognitive and emotional tasks are performed. Functional MRI does not measure neuron activity directly, but rather a signal corresponding to the complex metabolic modifications associated with it and which involve the entire neuro-vascular unit, i.e. also glial cells and capillaries. This the BOLD signal (Blood-Oxygen-Level-Dependent) which measures the differences in magnetic response between oxygenated and deoxygenated haemoglobin contained in red blood cells. When neural activity increases, there is an increased demand for oxygen and the local blood flow increases to satisfy this demand. However, since the blood brings more oxygen than is consumed by neurons, there is an imbalance in the concentrations of oxyhaemoglobin inflows and deoxyhaemoglobin produced, reflected as an increase in the signal.

The BOLD signal is therefore only an indirect reflection of neuronal activity. It cannot tell us if the activity of the neurons involved is inhibitory or excitatory, nor whether a lot of activity is ongoing in a small number of neurons or not much activity in a large number of neurons. Furthermore, the signal lags a few seconds behind the neuronal events whose timescale ranges from a millisecond to several hundred milliseconds.

Obtaining an image from raw BOLD signals is a complicated procedure. To begin with, the weakness of the signal being measured compared to the strength of background noise of cerebral activity is such that there has to be a repetition of the task under examination and of the data acquisition process, often involving a number of different subjects.

In the end, an average value is obtained so as to single out the signal corresponding to the activity under study from the clutter of background noise. The fact that it is frequently necessary to use a combination of studies involving several subjects **detracts from the individual significance of the data acquired.**

Images are then constructed using sophisticated calculation methods according to parameters which may be modified by the researcher according to conventional strategies which have an impact on the contents and visual appearance of the images. The complexity of these calculations is such that they require **expertise on the part of the researcher** and the image analysis must be validated by scientific theory. Image analysis must also take into account the subjects' considerable spontaneous or default mode brain activity which may contribute in varying degrees to activity being measured, increasing or decreasing for instance as a function of the subject's emotions.

To the extent that metabolic activation or inhibition observed on fMRI images is interpreted as an activation or inhibition of the activity of neuronal circuits, the quantity of activity shown on the images and the physiological importance of the task under way may not necessarily be proportionate.

The fact that an area of the brain generates a fMRI image is not an indication that the area concerned is devoted to one single function. Rather, the area would be included in the functional networks which are formed and dissolved depending on the cognitive task to be undertaken. The cerebral regions which are activated or inhibited are part of a system of neuronal circuits organised and distributed topographically, with cerebral areas where neuronal traffic is intense contrasting with neuronal pathways which are largely unused. In other words, the region which activates a maximum number of nerve cells, in conjunction with metabolic activation, is not necessarily the one which has the most significance in functional terms[3].

To sum up, the BOLD signal on which the fMRI method is based is an indirect reflection of neuronal activity, which can only be distinguished from background noise once repeated measurements have been made, and it requires complex processing before it can produce an image. As a result, **the final image is not a photograph of neuronal activity** and **its individual significance is weak.**

I - 2 Functional MRI clinical research

Despite these limitations, fMRI is an exceptional research tool for the study of normal and pathological brains. But **it also provides applications in clinical practice, such as diagnosing states of awareness in non communicating or poorly communicating patients** (coma, vegetative states, minimally conscious states, etc.), evidencing functional cerebral regions to be spared in the event of neurosurgical excision, rehabilitation of various neurological deficits (paralysis, impaired vision, neglect, etc.) and the treatment of severe neuropathic pain before possible motor cortex stimulation therapy.

The following are two examples:

1) In "non communicating" patients, as they are termed, there is a continuum ranging from a normal state of awareness to coma, with

[3] Hervé Chneiweiss: "The existence of functional areas is not a presumption of a functional brain and the existence of information processing cannot prejudge on the capacity of consciousness", *OPECST* (*Office parlementaire d'évaluation des choix scientifiques et technologique*), introduction, *Exploration du cerveau, neurosciences : avancées scientifiques, enjeux éthiques*, record of a public hearing on Wednesday, March 26, 2008, p.10.

complex intermediate conditions such as persistent or continuous vegetative state (PVS) in which patients do not show any signs of awareness, either of themselves or of their environment. Results of research by teams headed by A. Owen[4] (Cambridge) and S. Laureys (Liège), based on an fMRI study of a young woman in PVS, have completely overturned this concept. The young woman was asked by the researchers to imagine that she was playing tennis. While no clinical reaction was observed, brain activity was recorded which was identical to that of healthy volunteers given the same instructions. This exceptional observation, which has a potential for clinical applications[5], raises a large number of clinical neuroethical queries touching on various issues — not the subject of this Opinion — such as major disabilities, end of life and brain death criteria.

2) The same fMRI techniques could be used for the purpose of enhancing individual physical capacities. Understandably, the technique might be welcome to alleviate the sufferings of people with a motor handicap or in pain. They could learn to modulate certain cerebral activities to attenuate the handicap: work done by a team of neuropsychologists from Lyons[6], under the leadership of Ms Angela Sirigu, shows how people represent in their brain the movement of an upper limb that was in fact amputated. Movement can therefore be perceived without the hand itself actually moving and neuronal activation corresponding to that movement can occur in the brain even though the limb involved is phantom. This fact as observed could help to improve the technique for grafting a bionic arm.

II Ethical issues arising out of fMRI-based research

II.1. fMRI research domains

II.1.1. Evaluating mental faculties?

There are instances of recent research presenting fMRI as an instrument capable of providing information on the psychology of an individual. It is true that it can identify cerebral structures preferentially involved in powerful emotions such as fear or disgust (Whalen, 1998), or in addiction (Childress, 1999). Such studies, however, were conducted in situations far removed from any spontaneous or everyday occurrence.

Functional MRI has also been used in attempts to understand the cerebral mechanisms underlying the action of “decision making” on the part of, for instance, a consumer or policy makers. How should we view work aiming to detect a complex attitude such as deceit or antisocial behaviour? There seems to be growing interest in

[4] Adrien M.Owen’s group published an article on this subject in 2006: Detecting Awareness in the vegetative State, 313, Sci.1402 (Sept.8, 2006).

[5] It would be theoretically possible, if the status of the patient’s brain could be "monitored" in real time, to send a positive reinforcement signal and thus produce a closed loop in the system, which could possibly accelerate clinical rehabilitation (M. Lionel Naccache’s hearing).

[6] Centre for Cognitive Neurosciences UMR 5229 CNRS. Institute of Cognitive Sciences.

this type of study[7] touching upon a variety of subjects, such as the evaluation of violence (Illes et al, 2003) or the analysis of certain mystical experiences (Curran, 2003). Some doubts might be entertained regarding the scientific pertinence of such studies and their ethical implications: can the naturalisation of the mind claimed in this instance be allowed to dispense with anthropological and cultural data? **Is there not, through the total visibility that fMRI is supposed to confer, an infringement on personal privacy[8]? In this context, would it not be appropriate to voice a reminder that protection of privacy is an enforceable right?**

It should be pointed out that information on a person's personality obtained via fMRI is far from comparable with the data acquired through dialogue, discussion or as part of the doctor-patient relationship. The way in which fMRI images are produced and interpreted (cf *supra* the BOLD effect) precludes their use as a basis for forming a precise opinion on the beliefs, aspirations, thoughts and intentions of an individual.

Attempting to use[9] this technique is just as disputable when the aim is to enhance the cognitive capacities of human beings in a normal situation, in the same way as is the unjustified ingestion of medication[10]. In connection with this incipient transhumanism[11], **care must be taken to avoid diverting or overplaying the possible contribution of neuroimaging by taking it out of its medical context.**

The power of neuroimaging exerts such a degree of fascination that the concept of "mind-reading" is put forward as an operating proposition. Insofar as, in contrast to a discursive statement, an image cannot be challenged, there is an inclination to endow it with intrinsic interpretation whereas competence and rules must preside over its interpretation, and this competence and these rules[12] are not directly integrated in the image.

There has been some study of neuronal circuits in order to report on the processes occurring while reading or calculating. Stanislas Dehaene and co-workers, for example, using fMRI, observed changes in neuronal connectivity while learning to read. The aim was to observe how reading modifies cerebral organisation, how in particular the early visual areas are modified by the process of learning to read[13].

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7 Jorge Moll wrote in 2005 in "Nature": "The neurobiological validity of sociopathy and psychopathy is supported by imaging studies revealing a reduction of grey matter (...) Moral cognitive neuroscience can improve assessment, prediction and treatment of behavioural disorders". Jorge Moll *et al*: *"The neural basis of human moral cognition"*, Nature reviews Neuroscience, vol 6, 2005/

8 See Juha Räkkä, *Brain Imaging and Privacy*, in Neuroethics (2010) 3: 5-12.

9 Martha J.Farah 2005, *Neuroethics: the practical and the philosophical. Trends in cognitive sciences*, 9; 34-40: "Technological progress is making it possible to monitor and manipulate the human mind with ever more precision through a variety of neuroimaging methods and interventions. She adds: "The question is therefore not whether, but rather when and how, neuroscience will shape our future".

10 Ritalin, for example, a psychostimulant which is taken regularly for non therapeutic reasons by 4% of American adolescents aged 15 to 17.

11 This is "enhancement" medicine, i.e. non therapeutic medicine. Cf, the report by the U.S. President's Council on Bioethics: *Beyond therapy : biotechnology and the pursuit of happiness*, New York, 2003 and the collective work "Enhancement" *Éthique et philosophie de la médecine d'amélioration*. Vrin, 2009.

12 As Mme Claudine Tiercelin stated at the hearing, referring to the philosopher Ludwig Wittgenstein: it is neither the image, nor even its interpretation which constructs the link between the sign and its significance. It is through practice that this can be achieved, and only when complying with learning procedures and in context. Also cf the article "*Minds, Brains, and Norms*", by Michael S. Pardo and Dennis Patterson, in *Neuroethics*, published on line June 19th 2010.

13 Their observations reveal that the intensity of neuronal activity is directly proportional to the reading exercise which the people involved are engaged in. The aim is to "map the organisation of visual and auditory areas in the brain of

II.1.2. Identifying the semantic content?

Following from what is outlined above, there would be either continuity between the perception of an object and its semantic recognition at the neuronal level, or a "discreet"— i.e. separate — all-or-nothing phenomenon.

There are other opinions to the effect that there is discontinuity between the translation of an object perceived within a neuron network and its mental representation as a semantic content.

There have been several experiments (Haxby, 2001) to investigate these theories. One of them, for example, consisted in recording people as they were looking with attention at a variety of images of faces, animals, houses, kitchen implements, etc. The results showed that the pattern of activation recognised in the occipital visual areas (as expected) could lead to a correct classification of each of the objects according to the activation recognised by fMRI, with a 95% degree of accuracy. Even more suggestive, the same experiment was just as successful when the subjects were asked to imagine the objects (previously identified with fMRI), so that it was also possible to guess what object was being imagined simply by looking at the fMRI images (O'Craven et al, 2000).

The results of these studies seem promising: images observed in various parts of the active brain provide valuable information which could help to reinforce the results of previously validated neuropsychological tests.

These studies involving groups of healthy volunteers were conducted using low- or medium-powered MRIs; improved spatial resolution, however, can be expected from new high-powered MRIs.

Nevertheless, **results obtained so far cannot describe precisely the relationship between brain and thought.** The expressions used to attempt a description bear witness to difficulties, both experimental and theoretical, and to a conceptual deficit which is indicative of the caution which is required[14] in proceeding with an interpretation of the fMRI images. More than ever we are reminded that intellectual self-discipline must remain the rule where the relationship of brain to thought is concerned.

II.2. Ethical aspects of fMRI-based research

Functional MRI-research comes under the jurisdiction of the Huriet law governing biomedical studies applied to humans. It therefore requires, inter alia, the approval of a committee for the protection of participants, the submission of written information, informed consent, freely accepted participation, withdrawal rights and

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illiterates", to compare them with those of literates and thus to deduce the way in which education transforms cerebral circuits" in S. Dehaene, "Quand le recyclage neuronal prolonge l'hominisation" in Darwin 200 ans, directed by Alain Prochiantz, Odile Jacob, 2010, p. 129.

[14] Paul Ricoeur in his dialogue with Jean-Pierre Changeux listed the kinds of confusion which "prevail when correlation is unjustifiably transformed into identification", in in Jean-Pierre Changeux, Paul Ricoeur, *Ce qui nous fait penser*, Odile Jacob, Poches, 2000, p.49.

data anonymisation. **One very specific aspect of MRI research (be it functional MRI or not) is the frequency with which various unexpected anomalies are discovered.** Some, such as tumours and malformations can easily be interpreted, while others are of unknown significance. The frequency of these discoveries **increases with the power of the magnetic field.** It was, for example, 8.8% in a study on research MRIs on 525 healthy volunteers whose average age was 50[15]. The possibility of discovering such anomalies is justification enough for including a physician on fMRI research teams and the need for having neuroradiological expertise available if urgently required. Also, the strategies to be adopted in the event of an ethically delicate situation must be included in the consent form and must be spelled out very clearly. What is to be done if the MRI scan of a healthy volunteer, who does not wish to be informed of the results, reveals a tumour? What should be said to some one who wishes to see the results of his or her scan if anomalies are found which even specialists are unable to interpret?

There is therefore the issue of ethical behaviour on the one hand and the question **of the selection of fMRI-based research themes, on the other. This latter raises priority and pertinence issues.** Should clinically pertinent studies such as brain reorganisation after concussion or stroke for example, be considered less urgent than research on the sexual orientation of healthy volunteers?

Similarly, studies on "healthy volunteer" children in order to identify cerebral areas involved in shape and colour recognition are presented as pedagogical tools. They are much more questionable when they bear on psychological elements. The existence of a committee for the protection of participants and consent given by parents for their children to participate fully in the research are, of course, absolutely necessary. But the pertinence of such research also requires scientific evaluation and unfailing ethical vigilance.

III. Ethical issues arising out of the non medical use of fMRI

III.1. Risks incurred by the interpretation of mental faculties using fMRI

Using MRI scans outside the medical or scientific context may cause disquiet because of the risk of over-interpretation or of deviation from the intended purpose[16]. Indeed, the pretty coloured pictures produced by neuroimaging can give rise to false hopes or even to giving excessive attention to fantasies. Some popular magazines, when they publish headlines using expressions such as "the altruism centre", or "the neuronal basis for economic decision", etc., lend credibility to the illusion that imaging methodology reveals specific psychologies.

When addressing the general public, attention must be drawn to scientifically validated data. It is also important to watch out for some insurance brokers or

[15] Hoggard N et al J Med Ethics, 2009;35:194-199.

[16] The idea that there can be a genetic propensity for deliquency has already been expressed; there are bound to be attempts at using statistics found for certain types of population via functional imaging so as to have them coincide with certain types of behaviours. This could lead to creating not just a structure-function relationship, but also a structure-function-thinking relationship and to considering individual behavioural problems in that perspective.

recruitment agencies who may attempt to obtain neuroimaging information for the purpose of selecting candidates[17], which would be a violation of ethical principles.

As regards the evaluation of the thoughts of an individual, physiological fMRI-generated measurements are unreliable since they are only the correlate between an activity of the brain measured physically and frequently complex “mental processes”, such as the states and contents of consciousness, language, memory and perception. It would be misleading to speak of identifying a causal relationship using fMRI.

Visualising the modifications in metabolic activations and inhibitions can explain the ‘mechanics’ of how neurons perform or fail to perform when generating a preferred and expected behaviour, or a bizarre and catastrophic one. But this does not mean that a state of mind, a mental representation, a meaning or the cognitive contents transported by the neuronal circuits involved, can be read from their images. The image is not reality. In the same way as an idea does not resemble reality but only resembles another idea[18], an image only resembles an image. The concept of ‘blue’ is not blue itself and the concept of ‘dog’ does not bark.

Images are not, therefore, sufficient in themselves. They suppose the existence of rules of translation and interpretation, given in the context of a learning process which is related to the world[19] generally and not to just a brain.

It is not because a thought that comes to the mind of a subject when a task is proposed is represented by an image that the emergence of that image indicates a thought and therefore behaviour. The configuration of images observed translate neuronal firing, material phenomena, but these are not states of mind[20]. Even more consequential, fMRI images only become meaningful when they are confronted with a psychological context.

To sum up, fMRI observation reveals modifications of the activity of neuronal circuits globally, so that it becomes possible to identify the “neuronal routes” being followed, which does not mean having access to the contents or to the semantics of the message. **The fundamental message is that although behaviour is evidenced by an image, the image is not evidence of the behaviour.** There is therefore a risk of granting the status of “scientific truth” to brain imagery whereas this imagery is only the means of visualising cerebral markers of cerebral activity.

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17 T.Fuchs, 2006, *Ethical issues in neuroscience*. Current opinion in psychiatry 19 : 600-607. Fuchs discusses “the apparent objectivity of visualizing the ‘brain in action’, and the worrying tendency of “searching for the self in states of the brain”. He also notes that “The widespread misunderstanding that brain scans are direct measures of psychological states or even traits", ... "which carries the risk that courts, parole boards, immigration services, insurance companies and others will use these techniques prematurely".

18 George Berkeley objects to representative realism: “But say you, though the Ideas themselves do not exist without the Mind, yet there may be Things like them whereof they are Copies or Resemblances, which Things exist without the Mind, in an unthinking Substance. I answer, an Idea can be like nothing but an Idea; a Colour or Figure can be like nothing but another Colour or Figure." in *Principles of Human Knowledge*, first part, section 8.

19 Note cf Michael S.Pardo & Dennis Patterson, *Minds, Brains, and Norms,* In Neuroethics, published on-line on June 19th 2010: “Rule following occurs in a wide variety of contexts, each of which has its own unique features. These contexts are not “in the mind” (or “in the brain”) but in the world".

20 Philosophical attempts to reduce a state of mind to a neuronal state qualify as “reductionist materialism”, to quote the expression used by Claudine Tiercelin during her hearing, a materialism remaining subject to many a paradox.

III.2. Using functional MRI for non medical purposes and related misuses: legal aspects

Functional MRI, used for the decoding of brain activity, could have practical applications in today's world. In the judiciary area, lie detection has been a subject of research for quite some time and methods based on emotional responses have been in use here and there. We can refer here to C. Lombroso's lie detecting machine in Italy in the 19th century, to the use of the polygraph in the United States and to various forms "truth serum" which international treaties have classified as a form of torture. Deception is a complex language process which cannot be unveiled by the use of autonomous technology such as fMRI.

The Courts of Law [in France] are a case apart, since the July 7th 2011 law on bioethics gave the subject a degree of topicality which merits discussion. The law broadens the use of imaging techniques to forensic advice[21], beyond therefore the scope of medical research or treatment, whereas the *Office Parlementaire de l'Évaluation des Choix Scientifiques et Technologiques* (Parliamentary Bureau for the Evaluation of Scientific and Technical Options) had advised against the use of imaging techniques for judicial purposes.

However, those who approve of this extension argue that there is a need for some kind of framework to regulate the investigation of an injury so as to be able to compensate a potential victim. The rapporteur of the French Parliament's special committee[22] for the examination of the draft law on bioethics, makes it clear that brain imaging techniques will be used solely by derogation and "only in order to give concrete existence to an injury or psychological disorder". The rapporteur added that "It cannot be used as a lie detector".

Others express the fear that such methods could begin to be used as standard procedure as is currently the case, *inter alia*, in some North American[23] or Indian[24] courts, with obvious excesses. Since courtroom evidence system in France is based on an inquisitorial and not on an accusatorial procedure, there is not too much cause for alarm. Nevertheless, the existence of such unreliable procedures in certain countries

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21 Cf. Report of the Office Parlementaire de l'Evaluation des Choix Scientifiques et Technologiques, 17/12/2008.

22 February 2nd 2011.

23 See an article "Vers une neurojustice ?" (Heading for Neurojustice?) by the neurobiologist Catherine Vidal, Research Director, Institut Pasteur, published in "Ravages", n° 4, January 2011: "In the United States, explorations of the brain's anatomy and functioning, following on from the emergence of new imaging techniques has been in use for judicial purposes for some twenty years... In the 90s, Adrian Raine, a neurologist working in the University of California, was an expert witness in a trial for rape and murder. MRI imaging of the defendant's brain showed diminished activity of the prefrontal cortex which was supposed to explain his inability to inhibit impulses. As a result, he eluded the death penalty".

24 Also relevant is the case of a 24-year-old Indian woman who was found guilty in June 2008 by a court in Pune (Maharashtra) of poisoning her former fiancé. Her conviction was based in particular on the examination of her brain. An article in "Le quotidien du médecin" on April 6th 2009, gave a detailed account in which it was said that "the prisoner had accepted being submitted to a *Brain Electrical Oscillation Signature* (BEOS) test which was supposed to differentiate the electrical waves generated by the brain, depending on whether she was recognising, i.e. remembering, a known image or sound, or if on the contrary, the information was new to her... According to the court expert, the suspect's brain activity when the details of the crime were read out were proof of guilt, although she continued to protest her innocence".

should serve as a warning.

Many fMRI studies suggest that it would now be possible to detect lies or the concealment of information. Recently, several reports claimed to evidence different metabolic brain activations in people who were lying and people telling the truth (Langleben, 2002; Lee, 2002). In this way, by showing a suspect various people, objects or scenes connected to a crime, there is a belief that it should be possible to determine whether the subject's brain recognises an image stored in his or her memory, although the suspect denies any participation in the crime. **But is recognising an image, or being familiar with an image, evidence of having perpetrated an action or of having made a misleading statement[25] ?**

The supposed neuroimaging capability of detecting falsehoods has become so popular, despite the fact that the technique is still in its infancy and far from fully reliable, that commercial undertakings are now beginning to offer their services for lie detection using fMRI[26].

There is a need to sound an alarm regarding the risk of this technique obtaining excessive autonomy and thereby sweeping aside the cardinal principles of justice: cross-examination, ascertaining the truth on the basis of rival contentions, the defendants' right to keeping silent and refraining from incriminating themselves[27]. **In the circumstances, even supposing the use of fMRI-based techniques for lie detection is possible, is it desirable[28] ?**

The validity of expert evidence based on such investigative techniques, in the light of today's scientific knowledge, could well be declared inadmissible under the 1994 Daubert case law, which requires such evidence to be substantiated by scientific findings and accepted by the scientific community with expertise in that particular field. During one of CCNE's annual meetings[29], Counsellor Mario Stasi made the following point: "Is what we know of the situation in France regarding DNA records and secure custody while serving a sentence, not reason enough for defining without further ado the limits to be set for any application of neurosciences to the judicial domain? Or, in view of the possibly dangerous consequences of such use, should we not, at the very least, recommend in the strongest terms that unfaltering vigilance be exercised?

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[25] "To know something — knowledge that propositions about a crime are true, for example—is not located in the brain » in Michael S.Pardo & Dennis Patterson, *Minds, Brains, and Norms*, In Neuroethics, published on line June 19th 2010.

[26] Lawrence Farwell, "formerly a neurobiologist from Harvard University, heads a company by the name of Brain Fingerprinting which sells 'truth tests' for court cases or private disputes, but also to the advertising industry so that they may find out what consumers remember about a commercial... Dr. Farwell's test was sold under the brand name BEOS (Brain Electrical Oscillation Signature Test) by Champadi Raman, a former Head of the Psychology Department of the National Health Institute in Bangalore. He was able to have the judicial authorities in two States, Maharashtra and Gujarat, agree to making the technique admissible in court, so that in these two States, 75 suspects and witnesses took the test," in *L'Express* of March 6th 2009.

[27] We wish to thank Monsieur Jean-Claude Ameisen and Monsieur Mario Stasi for having drawn our attention to these points.

[28] How could the risk be avoided of using biological indicators as indicators of whether people are dangerous? Hervé Chneiweiss remarks: "What should be done if images reveal that an individual is not entirely capable of controlling his or her violent impulses?" He adds: "The problem is therefore, once again, to determine the true predictive value of such a test".

[29] 20th and 21st January 2011 on the theme: Who is 'normal'?

IV. Confidentiality and data protection

Imaging data must, of necessity, be computerised, if only because of the way it is acquired and even more so because of the large number of images. In the main therefore, they are now stored and protected electronically instead of only physically. However, "Increasing computerisation of medical data is taking place in a cultural climate of mistrust" [30]. Currently, the computerised storage of radioimaging data is on the increase and is done using PACS (Picture Archiving and Communication System) with which it is possible not only to store and archive images, but also to transmit them digitally. Scanning and storing medical images using such systems is becoming ever more widespread, both in public and private health institutions. Access to images in storage is enabled through a personal access code system available to authorised personnel, i.e. mainly to the doctors who produced the images and those involved in related treatment. According to rules and regulations drafted by the CNIL[31], every instance of 'access' to a computerised case file for a particular patient gives rise to a 'trail' with the date, time and code used, so that the 'visitor' can be identified. Checking procedures are therefore post-factual so that it can be known who accessed what information, when and in which file[32].

The procedure for the frequency of such checks by the host — whose task and duty it is to proceed with such checks — must be specified and adhered to. The discovery of an unauthorised and unjustified visit must give rise to an identity search and appropriate consequences. Furthermore, data anonymisation must be provided if the patient so requests.

Depending on the origin and context of image acquisition, three situations may arise:

1 - The neuroimaging data is part of the medical case file.

If so, they fall into the ordinary category of conservation and confidentiality of medical data. The creation of a medical case file and its conservation are mandatory by virtue of article 45 of the Code of Medical Deontology. The documents are kept under the doctor's responsibility. Article 73 of the Code of Medical Deontology reiterates that the protection of confidentiality is an obligation. These general rules also apply to computerised neuroimaging data according to procedures quoted above, both in private practice and medical

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[30] CCNE's Opinion n° 104. See also the report of an OECD working group on neuroinformatics which said that the creation of the first human brain atlas on the internet, based on over 7,000 human brains, could, in the long term, raise privacy issues. This was quoted in the *Rapport de la mission d'information de l'Assemblée Nationale sur la révision des lois bioéthiques du 20 janvier 2010* (French Parliament mission on the revision of the bioethics laws of January 20th 2010).

[31] Cf. *Guide CNIL professionnels de santé*, (CNIL guide for healthcare professionals) 2011 edition, internet website: www.cnil.fr

[32] There are undefined fears that unwarranted uses of the information obtained and its predictive impact on the judicial system and insurance companies could be a violation of privacy and patient autonomy. In its Opinion n° 98, on biometrics, CCNE utters a word of warning: changing the purpose of biometrics can end up being a misappropriation of purpose when biometric data is used in violation of personal rights of privacy. In the name of security, our society "is becoming accustomed to biometric markers and everyone seems resigned and even indifferent to being registered, observed, tracked and traced, often unwittingly". (CCNE's Opinion n° 98 on Biometrics, identifying data and human rights.)

institutions[33].

2- **The data is the end result of biomedical research**. The conservation and protection of data confidentiality are regulated by the 1988 Huriet Law on biomedical research and it is the duty of the project promoter's research director to ensure that the law is applied. In particular, research using fMRI — be it for examining patients with a view to gaining a better understanding of the management of pathological conditions, or based on healthy volunteers in order to progress in the understanding of the way in which the brain works — must be registered as part of a biomedical research project and therefore governed by all the rules and regulations that this entails.

3- **The last of these three situations bears on personal data or a collection of data relating to a particular group of people, put together by private and non medical structures,** such as those quoted above in chapter 3.2. In this case, no information is given on how the data is collected nor on how it is protected. The issue which arises, over and above the question of data confidentiality and conservation, is that of authorising or limiting the use of such examinations, using MRI and fMRI in particular, in a setting and a structure which is concerned neither with medical treatment nor with scientific research.

Cyber protection of the confidentiality of private personal data, in particular those relating to mental faculties, is an imperative. With or without consent, neuroimaging data and its interpretation could become accessible to third parties. **Even more significant, three-dimensional imaging obtained with MRI raises the new issue of face recognition using facial reconstruction methods.** "The availability of this multitude of images could, *de facto,* eliminate any kind of confidentiality. .... The ease of communication and data processing provided by computers should not do away with the need to exercise critical judgment. On the contrary, their presence makes it all the more necessary" [34].

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[33] Code de déontologie médicale (Code of Medical Deontology); site : www.conseil-national.medecin.fr

[34] CCNE Opinion n° 104. The "Personal Medical Record" and computerisation of health-related data.

Conclusions and Recommendations

The MRI revolution, that is the advent of a non invasive method for studying the structure and physicochemical composition of the brain, is an unassailable fact. The use of this method for diagnostic, prognostic and therapeutic purposes has been a factor for remarkable progress in the management of patients suffering from disorders affecting the brain, and also for furthering our knowledge of such conditions.

Furthermore, **the hopes pinned today on fMRI procedures in order to understand the way in which the brain works, are legitimate and their applications are increasingly numerous and fruitful[35].**

Prospective studies exceeding the bounds of medical practice must take into account the indirect nature of the measures made and their time lag: **psychological states are not being directly measured, nor can character traits be revealed by simply interpreting the images.**

An image is not a photography of neuronal activity. Such activity is of course modified by cognitive tasks, by emotions, by what the brain is doing, but are such tasks limited to the brain activity which is under observation?

Nor are fMRI-generated images immediately connected to thought; they are linked to the activity of the neurovascular unit. **This means that although a certain behaviour may be linked to a particular image, the image itself does not point to a specific behaviour.** There is a risk, even perhaps a likelihood of ethical misuse if this technique is brought into play too early and too freely. Some of these risks are connected to the interpretation of fMRI scans and others to their use.

CCNE recommendations:

- Exercise **the utmost vigilance** at a time when increasingly, fMRI is used for so-called truth tests, and tests for evaluating personality and mental functions, since there is a risk of reducing human complexity to what can be expressed by functional imaging data and a risk of believing in the illusion that this technique offers complete certainty[36].
- **Only relate fMRI images to the scientific theories on which they are based** and to the rules of interpretation with which they can be deciphered.
- **Resist the fascination of fMRI-generated images** and consider them as no more than a contribution for enhancing probability within an extensive range of arguments.
- Take care to interpret the mental activity of individuals only within the frame of

[35] Similar hopes also exist for other procedures, see Annex 2.

[36] Care must be taken to avoid falling for “a new brand of clairvoyance”, to quote Mme Mary-Hélène Bernard.

reference of their social environment, taking into account learning, context and experience.

- Ensure that research using neuroimaging techniques — be they applied to patients or healthy volunteers — is contained within the **regulatory framework of biomedical research.**
- Be extremely wary of the consequences of insufficient protection of MRI or fMRI images, **encourage systematic anonymisation of images stored** in computerised data banks and implement protocols for supervision when access is granted to such computerised data.
- When neuroimaging techniques are used outside the area of medical research, make sure **that their use, particularly in a judiciary context, as the bioethics law dated July 7th 2011 provides, is strictly controlled so that it does not give rise to discrimination.** Rules for the use of fMRI should be precisely defined along the same lines as those currently laid out in the Code of Public Health and employment legislation regarding genetic data.
- **Intensify ethical vigilance** in the light of the very rapid development and increased sophistication of techniques for exploring the brain and its functions.

Paris, 23rd February 2012

Annex 1

The human nervous system

The nervous system is composed of several parts:

1) Nerves. They send sensory signals to the brain (senses of touch, sight, hearing, smell, taste) and make movement possible by activating muscles;
2) The spinal cord. It relays signals from nerves to brain and vice-versa;
3) The cerebellum. In the main, it coordinates movement and balance;
4) The basal ganglia and the thalamus act as relays for afferent pathways of perception, attention and body movement;
5) the brain itself, enabling all the mental functions.

The human brain is a mass of nerve cells weighing on average 1350g and is of unparalleled complexity, as the number of neurons testifies: humans have some 85 billion neurons, each of them has a myelin sheathed axon and dendritic extensions, exchanges between a thousand and ten thousand connections with its neighbours and produces around a thousand signals per second. The whole brain therefore would be generating about one hundred million billion signals per second.

There are an even greater number of supporting cells, called glial cells, which are part of a fibrous network filling the spaces around the neurons. All together, neurons, glial cells and blood vessels, make up a neurovascular unit forming one integrated whole in terms of anatomy and function. Exchanges between the three components of the unit are produced through variations in blood flow: as neuronal activity increases, so does the flow of blood. Conversely, a reduction in blood flow can lead to neuronal distress.

Metabolic modifications have been observed for several cell types. Mostly the neurons are involved, particularly in nerve endings (where metabolic activity is high) and, but to a lesser degree, in the cell bodies and their dendrites. But there is also metabolic activity in the glial cells around the neurons, in numbers of at least twice those of the neurons.

Recent advances in anatomy and physiology have at last given us an understanding of some brain functions, although such progress is still in its infancy. For a more adequate approach of the ethical issues involved in the study of the brain using imaging, it is convenient to distinguish between three levels of complexity:

– At the phylogenic level, the brain has evolved along three lines, from bottom to top: first the nerves and the spinal cord, then the brainstem controlling all vital functions (breathing, arterial blood pressure, etc.). Later, starting in the Age of Fishes, the "reptilian" brain appeared, including the basal ganglia, which are situated in the centre of the brain on either side of the midline and are associated with automatic behaviours. Still later, reaching maximum development with primates, including homo sapiens, the "mammalian" brain evolved, consisting of the cerebral cortex (a thin sheet 3-5 mm in thickness, situated at the brain's periphery and containing approximately 20% of the neurons.

- At the ontogenic level, nerve cells have such a high capacity for migration and adaptation that, although they do not multiply (except in a limited way in certain specific areas of the brain), they are able to construct the nervous system during embryogenesis and the whole of childhood (at birth, the brain's weight is about 25% of the adult's). Nerve cells are therefore endowed with sufficient "plasticity" to enable an adult to learn and adapt. During this process, the cells modify their metabolism in the form of anatomic modifications. One example of such modification is the regrowth of nerve endings to replace those which may have been destroyed.
- At the physiological level, the brain can be more conveniently considered according to the following distinctions: the distinction between a posterior part of the brain receiving perceptual messages and an anterior part which controls the execution of behaviours. It is also convenient to conceive of neuronal circuits (series and parallel connections) specialised in the management of three major functions:

1) motor function (movement executed by the activation of 'sensorimotor' neural circuits);
2) emotional function, ranging from emotion to the most subtle of feelings (the 'limbic' neural circuits, as they are called);
3) intellectual function, such as reasoning, judgment, memory, language (the so-called 'associative' neural circuits).

Annex 2

Methods for the exploration of the human brain

1. Exploring the brain

For many centuries, the only way in which the brain could be examined was anatomo-clinically, based on a comparison between the post mortem macro- and microscopic examination and the earlier clinical observations, which in some cases dated back a number of years. This was the method which led to the development of the entire discipline of neurology. The advent of new methods of exploration has led to anatomy being replaced by imaging, but has in no way diminished the primary importance of clinical observation, be it for the practice of medicine or for research.

Up to the early 1970s, the tools available to practitioners were already capable of studying spontaneous or provoked neuronal activity in the form of electrical signals acquired via electrodes attached to the subject's scalp (electroencephalograms and evoked potentials), or more directly through the study of cerebral blood flow modifications. But the brain itself remained invisible. Its morphology could only be apprehended indirectly by displaying the bone (skull x-ray), the blood vessels (angiography) and the cavities containing the cerebrospinal fluid (gas encephalography, venticulography).

In 1971, for the first time, a brain scanner (the computed axial tomography/CAT scan) made it possible to see the brain of a living subject and display it in the form of a stack of slices, rather like those of anatomists. The concept, a revolutionary one at the time, was to apply x-ray beams around an axis and to use a computer to reconstruct three-dimensionally the data acquired. A scan is therefore a radiography of the brain displayed in axial planes. A second revolution ten years later was MRI, magnetic resonance imaging, which is based on the detection of signals generated by magnetic fields internal to the brain so that its structure and functioning can be studied in much greater detail.

Many other methods for exploring the brain were later developed, such as the PET scan (Positron Emission Tomography), an excellent tool for research and also very useful for clinical purposes, in particular for cancer, but of limited access since it requires the proximity of a cyclotron; isotope tomoscintigraphy, less informative but used more routinely; and magnetoencephalography (MEG) which analyses brain activity by recording electromagnetic data. Other new tools are in the process of development, using for example ultrasound, infrared or optical imagery (e.g.: optogenetics.

However, out of all these various methods, MRI currently has pride of place since, as noted above, it is the one which is the most informative on the structure (MRI) and the functioning (fMRI) of the brain. And it is the method most commonly used in clinical practice and for research.

2. Nuclear Magnetic Resonance imaging, or MRI

The MRI technique is based on the use of a powerful magnetic field in the shape of a kind of tunnel, inside which patients are asked to lie down and keep their head still[37]. Under the effect of the magnetic field, hydrogen atoms become aligned, like so many small magnets, after which they are briefly stimulated with radio frequencies. When these stimulated atoms return to their relaxation state, they restitute the accumulated energy by emitting a signal. Its electronic processing along with three-dimensional reconstruction produces the required images. Depending on the technical parameters which are applied, which may be modified by the operator, various "sequences" are run, each one lasting several minutes, supplying different kinds of images according to the physicochemical properties of the structures under study. The name of these sequence refer in some cases to the technical parameters used (*T1, T2, according to the hydrogen atom relaxation times, FLAIR (Fluid Attenuated Inversion Recovery), Gradient Echo)* and in other cases to what they are measuring *(diffusion and perfusion sequences).* Or they may refer to the use that will be made of the results of the examination *(Magnetic Resonance Angiography/ARM, Magnetic Resonance Spectroscopic Imaging/MRSI, Functional MRI).* For example, the highly anatomic T1 sequence shows clearly the contrast between grey and white matter; the diffusion sequence, which is particularly sensitive to the movement of water molecules, can reveal cerebral ischemia at a very early stage and can also map white matter directions *(tractography);* the blood vessels in the head can be displayed using ARM, and spectroscopic MRI provides very useful metabolic data, particularly in the event of a tumour. The above goes to show that the concept of "normal cerebral MRI" is meaningless if the sequences used —which are in principle chosen by the operator depending on the wishes of the clinician or the research scientist concerned — are not specified.

The degree of precision provided by MRI depends on the spatial resolution of the apparatus, which is itself dependent on the power of the magnetic field: 1.5 to 3 Tesla (*the magnetic induction unit named after the physicist Niko Tesla*) in clinical practice. With 7 or even 11 Tesla used for research purposes, the precision would be of the order of 100µmm, but the risks are yet to be evaluated.

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37 MRI is in fact dangerous for subjects implanted with ferromagnetic objects such as pacemakers and defibrillators. Claustrophobic patients feel extremely uncomfortable inside an MRI scanner and it may be necessary in their case to administer general anaesthesia. Furthermore, the magnetic field generator is exceptionally noisy so that some form of hearing protection is required.