

**NEUROETHICS****Neuroscience of decision making and informed consent: an investigation in neuroethics****Georg Northoff***J Med Ethics* 2006;**32**:70–73. doi: 10.1136/jme.2005.011858

Progress in neuroscience will allow us to reveal the neuronal correlates of psychological processes involved in ethically relevant notions such as informed consent. Informed consent involves decision making, the psychological and neural processes of which have been investigated extensively in neuroscience. The neuroscience of decision making may be able to contribute to an ethics of informed consent by providing empirical and thus descriptive criteria. Since, however, descriptive criteria must be distinguished from normative criteria, the neuroscience of decision making cannot replace the ethics of informed consent. Instead, the neuroscience of decision making could complement the current ethics, resulting in what can be called neuroethics of informed consent. It is concluded that current progress in the neurosciences could complement and change the way in which we approach ethical problems in neuropsychiatry.

be traced back to specific changes in brain function. The very same affective and cognitive changes associated with respective disorders may also contribute to these patients' impaired ability to give valid informed consent.

A neuroethics of informed consent raises empirical and conceptual issues. Empirical issues concern the specific psychological and neuronal processes that are involved in the particular type of decision making that characterises informed consent. Investigation of the psychological and neural processes of decision making could contribute to the establishment of empirical criteria for valid informed consent.

Conceptual issues concern the principal relationship between neuroscience and neuroethics as well as the definition of the brain. Naturalistic accounts may ultimately claim for the replacement of neuroethics by neuroscience and a purely physical definition of the brain, whereas non-naturalistic accounts need to clarify the relationship between neuroscience and neuroethics, thereby developing a more complex definition of the brain.

The aim of the present article is to discuss both empirical and conceptual issues of informed consent. I presuppose a concept of informed consent that involves both complex psychophysiological processes of decision making and normative values reflecting the respective socio-cultural context. My claim is that the neuroscience of decision making can contribute to the development of empirical criteria for valid informed consent. In contrast, I do not claim that the neuroethics of informed consent can be replaced by the neuroscience of decision making; this would mean neglecting conceptual issues and ultimately confusing the descriptive and the normative levels. Neuroethics is thus understood as an amalgam of ethics and neuroscience in which descriptive and normative levels are related to each other without either one becoming reduced or eliminated.

Recent progress in neuroscience has led to the demand for what has been called "neuroethics".<sup>1–3</sup> One of the most exciting aspects of this field is that neuroscience will allow us to reveal the psychological and neuronal processes involved in ethically relevant notions. For example, recent imaging studies investigating the neuronal correlates of moral judgement<sup>4–6</sup> show that moral judgement activates specific regions in the brain such as the medial prefrontal cortex. This raises several questions: Does moral judgement consist of nothing else but the activation of certain regions of the brain? Do we have to consider moral judgement as being brain based? Do we have to replace what we so far have called moral decisions by particular types of brain activity?

The same questions must be raised in the case of informed consent. This involves a psychological process of decision making that can be related to specific types of neuronal activity. Furthermore, patients with neuropsychiatric disorders such as Alzheimer's disease often show an impaired ability to give informed consent.<sup>7</sup> This renders their informed consent invalid—it becomes an impaired consent. Similarly, patients with other neuropsychiatric disorders such as depression or schizophrenia are often unable to give valid informed consent. What do these diseases have in common? They all lead to severe emotional and/or cognitive disturbances that can

**EMPIRICAL ISSUES****Psychological processes in decision making and informed consent**

Which neuropsychological functions are necessary for the decision making involved in giving valid informed consent? The often used MacArthur Competence Assessment Tool – Treatment (MacCAT-T)<sup>8</sup> relies predominantly on cognitive abilities such as understanding, appreciation, expression of choice, and reasoning.

**Abbreviations:** IGT, Iowa Gambling Task; MacCat-T, MacArthur Competence Assessment Tool – Treatment

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In contrast, emotional abilities are rather neglected. However, considering recent empirical studies, the inclusion of emotional abilities seems rather urgent. Relying on the Iowa Gambling Task (IGT), Damasio demonstrated that decision making is guided and modulated emotionally.<sup>5</sup> It requires subsequently not only cognitive function, as is often presupposed, but also emotional function. This is further underlined by neuropsychiatric disorders. Patients with diseases that cause severe alteration in the interplay between cognitive and emotional functions (for example, catatonia) show major impairment by achieving low scores in the IGT, reflecting emotionally guided decision making.<sup>9</sup> Correspondingly, these patients are also unable to give valid informed consent.<sup>10</sup>

The decision making involved in informed consent can subsequently be described by the interplay between emotional and cognitive functions. How can we investigate this empirically? An appropriate scale measuring neuropsychological function in informed consent should include both cognitive and emotional abilities. A first step in this direction would be to administer both the MacCAT-T and the IGT in people who have deficits in decision making and in giving valid or invalid informed consent, and to correlate both types of scales. Specific correlation between the MacCAT-T and the IGT would strongly suggest an interplay between cognitive and emotional functions in the decision making involved in informed consent. This first step could be followed by additional steps of empirical investigation of specific interactions between cognitive and emotional functions. For example, cognitive function could be specified into working memory, executive function, etc. Analogously, emotional function could also be differentiated into distinct operations such as emotional experience, emotional expectancy, emotional judgement, etc.<sup>11 12</sup>

### Neuronal basis of decision making and informed consent

What is the neural basis underlying the interplay between emotional and cognitive abilities in decision making involved in informed consent? Cognitive abilities require predominantly working memory and executive function, which, in turn, are closely related to the function of the lateral prefrontal cortex.<sup>13</sup> In contrast, emotional function is associated with neural activity in the medial prefrontal cortex.<sup>5 11 12</sup> The interplay between emotional and cognitive functions is subsequently mediated by the balance between the medial and lateral prefrontal cortices.<sup>11 12</sup>

Can prefrontal cortical function be directly related to decision making involved in informed consent? This could indeed be so—for example, this could be investigated using functional magnetic resonance imaging. Using this technique, one can easily compare the task of giving informed consent (as an activation task) to other decisional tasks (as control tasks). Unlike an activation task, decisional tasks should involve neither the decision maker nor any decisions that he or she may make about future diagnostic/therapeutic procedures. If my hypothesis of prefrontal cortical involvement in decision making during informed consent is correct, the difference between the two decisional tasks should consist of a specific pattern of neural activity across the medial and lateral prefrontal cortices. In another possible study one might—for example, disrupt prefrontal cortical function by applying transcranial magnetic stimulation.<sup>14</sup> This artificial disruption of informed consent would allow the researcher to infer possible neuronal correlates that could eventually prove to be indispensable in the treatment of deficits in decision making associated with impaired consent (see also below).

### Diagnosis and therapy of deficits in decision making and impaired consent

How does elucidation of the psychological and neurological processes of decision making contribute to the development of empirical criteria for informed consent? Once the psychological and neuronal processes of decision making involved in informed consent are known, we should be able to diagnose and treat deficits in decision making, which would then contribute to the restoration of valid informed consent.

Knowledge of the underlying patterns of neuronal activity would provide empirical (that is, brain based) criteria for diagnosing deficits in decision making associated with impaired consent. For example, emotional dysfunction as well as neural dysbalance between the medial and the lateral prefrontal cortices could be considered diagnostic markers of deficits in decision making. Since decision making is crucial in informed consent, such diagnostic markers can be considered as empirical criteria of an impairment in informed consent. The conceptual criteria of informed consent, as discussed in current bioethics, can thus be complemented by empirical and brain based criteria as established in neuroethics.

Means of treating neural prefrontal cortical dysbalance and restoring the balance between the medial and the lateral prefrontal cortices may be developed in the future, allowing for “normal” emotional–cognitive interactions in decision making. Since decision making is involved in informed consent, the restoration of these emotional–cognitive interactions could also affect a person’s ability or inability to give valid informed consent. For example, electrodes could be implanted in or transcranial magnetic stimulation applied to the medial or lateral prefrontal cortex in order to remodulate the neural dysbalance and then to treat deficits in decision making, which, in turn, could contribute to restoring the ability to give valid informed consent. Prefrontal cortical function may then be considered to be a therapeutic marker of intact decision making involved in informed consent. Since, however, we currently lack insight into the neuronal correlates of decision making associated with informed consent, brain based therapy for deficits in decision making with consecutive restoration of impaired informed consent remains a futuristic scenario.

## CONCEPTUAL ISSUES

### Neuroethics and neuroscience

Can we identify the empirical criteria for decision making during informed consent? Can we replace the ethical notion of informed consent by the psychological and neural processes underlying decision making; would it be better to speak of the neuroscience of decision making rather than of the neuroethics of informed consent? This would mean that we can fully explain our moral and ethical notions in neuroscientific terms. Although we cannot discuss such naturalistic accounts of ethics in its entirety, I at least want to make some remarks concerning the possible (complete) naturalisation of informed consent in particular and neuroethics in general.

How would a naturalistic account of informed consent appear? Decision making involved in informed consent is a rather complex process that includes a variety of different psychological and behavioural states including intentions, beliefs, voluntary actions, etc. Only if all of these psychological and behavioural states could be shown to be necessarily and sufficiently dependent upon physical brain function could a naturalistic account be considered. If informed consent can indeed be identified completely with decision making, it could be accounted for in naturalistic terms.

This, however, would mean neglecting the distinction between the descriptive and the normative levels. Empirical criteria by themselves are purely descriptive, not involving any normative implications. Once however the validity and relevance of empirical criteria for informed consent are discussed, normative issues come into play. This allows for balancing the various empirical criteria of decision making with respect to their importance for valid informed consent in a given context. Normative issues are no longer considered in naturalistic accounts of this topic because informed consent is identified with decision making; this implies unilateral predominance of the descriptive level while the normative level remains neglected. Ultimately, this leads to the complete replacement of both ethics and neuroethics by neuroscience.

The naturalistic replacement of ethical notions by neuroscientific terms implies that the distinction between empirical and conceptual issues is no longer maintained and is replaced by the predominance of the former. The empirical criteria for decision making are then considered the only and exclusive criteria for informed consent. Informed consent becomes a purely empirical matter, no longer involving any conceptual issues—for example, those discussed here. The neuroethics of informed consent thus becomes replaced by the neuroscience of decision making.

Finally, the question of the mind–brain relationship needs to be considered in discussing the relationship between neuroscience and neuroethics.<sup>15</sup> Any naturalistic account of informed consent must presuppose a naturalistic mind–brain relationship tracing mental terms and concepts back to the physical properties of the brain. However, recent debate in the philosophy of the mind (like—for example, Chalmers<sup>16</sup>) and even some neuroscientists (Penfield,<sup>17</sup> Eccles<sup>18</sup>) challenge a naturalistic account of the mind–brain relationship. Since naturalism itself remains problematic, it becomes questionable whether a naturalistic mind–brain account should be presupposed in our case of informed consent. Accordingly, the complete replacement of the ethics and neuroethics of informed consent by the neuroscience of decision making could turn out to be more problematic than the naturalist might have initially thought.

### Definition of the brain

I have distinguished between the empirical and conceptual criteria of informed consent. Empirical criteria rely on the psychological and neural processes of decision making involved in informed consent. Here the brain itself is the focus of investigation because it is considered to be necessary and sufficient for generating the respective psychological and neural processes. The brain in decision making is characterised by an exclusive focus on the physical processes within the brain itself remaining isolated from its respective environmental context. One can subsequently speak of an “isolated brain”.<sup>15</sup> Since a naturalistic account relies exclusively on physical (that is, empirical) criteria, a naturalised concept of informed consent in terms of decision making presupposes the brain to be an isolated brain.

Empirical criteria remain purely descriptive by themselves and therefore do not imply any norms and values; instead, they are provided by conceptual criteria being normative. These norms and values are reflected in our concept of informed consent, which therefore cannot be identified with the merely empirical function of decision making. Any discussion of norms and values is possible only when one considers the respective cultural and social context—that is, the environment. Since it refers to norms and values, informed consent, unlike decision making, presupposes a relationship to the respective environmental context. If one wants to associate informed consent with the brain, one

should therefore consider the brain in relation to its environment—that is, as an “embedded brain”.<sup>15</sup> A non-naturalistic account distinguishes the normative from the descriptive level, so a non-naturalistic concept of informed consent should presuppose the brain as an embedded brain.

Taken together, the brain as an isolated brain is presupposed to underlie decision making, whereas the brain as an embedded brain must be affiliated with informed consent. If one identifies informed consent with decision making, as in naturalistic accounts, the distinction between the isolated and the embedded brain can no longer be maintained. Although the reasons cannot be discussed here, equating the isolated with the embedded brain is neither empirically nor conceptually plausible.<sup>15</sup> The need for distinguishing between the isolated and the embedded brain in empirical and conceptual ways thus presents a strong argument against a naturalistic concept of informed consent in terms of decision making because then the distinction between both kinds of brain must be resolved. A non-naturalistic concept of informed consent is thus suggested. Such a concept no longer reduces informed consent to mere decision making and associates it with the embedded rather than with the isolated brain.

### The ethical dilemma of impaired consent in a naturalistic account

A naturalistic account presupposes identification of the brain of decision making with the brain of informed consent. This poses an ethical dilemma, with two alternative ways of acting when there is impaired consent that are both ethically unacceptable. I will therefore call this dilemma “the ethical dilemma of impaired consent”.

In the case of a neuropsychiatric disorder, the brain of decision making needs to be treated and must thus be considered as the target organ for therapy. In contrast, the brain of informed consent is essential for giving approval to such treatment and could thus be considered the organ of informed consent. If, however, the brain of decision making and the brain of informed consent are presupposed to be identical, as implied in a naturalistic account, the following alternatives arise. Either the brain of decision making as the organ of therapy must be treated without any consent (unless relatives give consent) because, owing to its identification with the organ of informed consent, consent cannot be given without prior therapy. However, treatment without valid informed consent is non-acceptable ethically (except in life-threatening situations). Alternatively, the brain of decision making remains untreated because valid informed consent cannot be obtained. However, non-treatment of the patient’s symptoms and his or her deficits in decision making must also be considered unethical. Since either way of acting—treatment or non-treatment of the deficits in decision making—leads to an ethically unacceptable consequence, one is confronted with a dilemma: the ethical dilemma of impaired consent.

How can we resolve the ethical dilemma of impaired consent? Conceptually, it could be resolved by distinguishing between the brain of decision making and the brain of informed consent. The brain of decision making is characterised by the descriptive level and isolation from the environmental context; it is an isolated brain (see above). In contrast, the brain of informed consent is characterised by both the descriptive and the conceptual levels, with consecutive integration into the respective environmental context; it is an embedded brain. If the isolated brain and the embedded brain are distinguished from each other, as in a non-naturalistic account, the organ of therapy is no longer identical to the organ of informed consent. This implies that the ability to give valid informed consent is no longer

exclusively tied to decision making. Prior consent to the treatment of deficits in decision making remains no longer impossible and excluded; the ethical dilemma of impaired consent is resolved.

Empirically, the ethical dilemma of impaired consent can be resolved by what I call a two-stage therapy of decision making. The first stage would consist of treating those deficits in decision making that are crucially involved in impaired consent. The second stage, the treatment of disease-related symptoms, including those deficits in decision making that are not crucially involved in informed consent, will become possible once the patient can give valid informed consent. However, such a two-stage therapy is possible only if the neural correlates of decision making involved in informed consent are not exactly identical to those affected by the disease.

For example, the balance between medial and lateral prefrontal cortical function may be a crucial neuronal correlate of informed consent (see above). In contrast, the disease—for example, schizophrenia—may affect the medial temporal cortex (hippocampus) with its connection to the dorsolateral prefrontal cortex. This in turn could cause dysbalance of the whole prefrontal cortex, rendering informed consent invalid in these patients. In this case, two-stage therapy could possibly allow for the following scenario. In the first stage, ethical therapy could focus on rebalancing prefrontal cortical function in order to allow for valid informed consent. This in turn would enable patients to give valid consent to treatment of their symptoms—that is, neuropsychiatric therapy in the second stage. The focus of therapy could then be shifted from prefrontal cortical balance to a “normalising” function in the medial temporal cortex (hippocampus). Finally, it should be mentioned that such a scenario of two-stage therapy remains speculative at this point because it requires a much more fine-tuned investigation of neural and psychological functions than is currently available.

## CONCLUSION

Progress in neuroscience will allow us to reveal the neuronal correlates of decision making involved in informed consent. Such a “neuroscience of decision making” would allow us to develop empirical—that is, brain based—criteria of informed consent. Empirical criteria are descriptive and must therefore be distinguished from the normative criteria of informed consent. Normative criteria are characterised by norms and values and thus cannot be reduced to descriptive—that is, empirical—criteria. Therefore, the neuroscience of decision making cannot replace the ethics of informed consent.

Instead, it can complement the ethics of informed consent by providing empirical and thus descriptive criteria. I conclude that neuroethics, in such a complementary sense, will change the way in which we solve ethical problems of informed consent in twenty-first century neuropsychiatry.

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