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ORIGINAL ARTICLE

On/Off-Discrepancies in medical decision-making: utilising the reversibility of deep brain stimulation to strengthen patient autonomy

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Abstract

Definition of the problem Some medical interventions have the potential to interfere with patients' future healthcare decision-making. We identify two types of such influences: affecting whether a patient has decision-making capacity in the first place; and influencing which treatment option a patient ends up selecting.
Argument Using the example of deep brain stimulation, we argue that one should utilise this effect to obtain more authentic treatment preferences. In patients with implanted deep brain stimulators who do not meet the capacity threshold, the device state should be reverted as there is a chance that doing so has a positive effect on their capacity. In patients who are already deemed decision-competent, the same approach can reveal on/off-discrepancies in the selection of treatment choices.
Conclusion We propose five cross-checking strategies to deal with such discrepancies and call for a revision of current procedures for obtaining consent following *any* interventions whose psychotropic influences can be reversed within clinically reasonable time frames.

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On/Off-Diskrepanzen bei medizinischen Entscheidungen: Nutzung der Reversibilität der Tiefen Hirnstimulation zur Stärkung der Patientenautonomie

Zusammenfassung Einige medizinische Interventionen haben das Potential, zukünftige Entscheidungen von Patienten bezüglich ihrer Gesundheitsversorgung unmittelbar zu beeinflussen. Zu diesen gehören psychochirurgische Eingriffe, Psychopharmaka und bestimmte Formen der elektrischen Hirnstimulation. Wir unterscheiden zwei Arten solcher Einflüsse: Interventionen, die sich darauf auswirken, ob ein Patient *überhaupt einwilligungsfähig* ist; und Eingriffe, die beeinflussen, *welche Behandlungsoption* ein Patient letztendlich wählt.

Interventionen unterscheiden sich stark hinsichtlich der Reversibilität dieser psychotropen Effekte. Auswirkungen psychochirurgischer Eingriffe sind in der Regel permanent. Psychopharmaka weisen dagegen ein breites Spektrum an Halbwertszeiten auf, das von wenigen Stunden bis hin zu mehreren Wochen reicht. Der Schwerpunkt dieses Artikels liegt auf der elektrischen Hirnstimulation – insbesondere auf einer ihrer Varianten, die starke psychotrope Effekte haben kann, sich aber gleichzeitig durch eine vergleichsweise schnelle Reversibilität derselben auszeichnet: die Tiefe Hirnstimulation.

Am Beispiel der Tiefen Hirnstimulation argumentieren wir, dass diese Reversibilität genutzt werden könnte, um authentischere Behandlungspräferenzen zu gewinnen. Bei Patienten mit implantierten Tiefenhirnstimulatoren, welche die Schwelle zur Einwilligungsfähigkeit aktuell nicht erreichen, könnten Stimulationsparameter modifiziert werden, um einen möglichen positiven Effekt auf die Einwilligungsfähigkeit zu erzielen. Bei Patienten, die bereits als einwilligungsfähig gelten, kann derselbe Ansatz helfen, Konfigurationen aufzudecken, in denen geäußerte Behandlungswünsche in Abhängigkeit vom Gerätestatus differieren. Wir bezeichnen derartige Divergenzen als On/Off-Diskrepanzen.

Um On/Off-Diskrepanzen zu detektieren, schlagen wir vor, Präferenzen für Interventionsoptionen zweimal abzufragen – bei eingeschalteter und bei ausgeschalteter Hirnstimulation. Zeigen sich die Behandlungswünsche kongruent, können sie als von der Stimulation unbeeinflusst gelten, sodass kein weiterer Handlungsbedarf besteht. Fördert diese Gegenprüfung jedoch differierende Behandlungswünsche zutage, stellt sich die Frage, wie mit dieser Divergenz umzugehen ist. Wir schlagen fünf Strategien vor, um zu authentischen Präferenzen zu gelangen, und wägen ihre jeweiligen Vor- und Nachteile ab.

Während sich die elektrische Hirnstimulation durch eine vergleichsweise schnelle Reversibilität ihrer psychotropen Effekte für ein solches Vorgehen in besonderem Maße eignet, plädieren wir für eine Überprüfung der Entscheidungsfindungsverfahren nach sämtlichen Eingriffen, die erhebliche Auswirkungen auf die Einwilligungsfähigkeit von Patienten oder die Präferenz von Behandlungsoptionen haben können und deren psychotrope Einflüsse gleichzeitig – wie im Fall der Tiefen Hirnstimulation – innerhalb klinisch angemessener Zeiträume größtenteils vorübergehend rückgängig gemacht werden können. Sich diese Reversibilität zunutze zu machen, kann, so argumentieren wir, erheblich dazu beitragen, die Authentizität von Behandlungspräferenzen zu erhöhen und so die Patientenautonomie zu stärken.

Schlüsselwörter THS · Entscheidungsfindung · Authentizität · Präferenzen · Einwilligungsfähigkeit

Introduction

Healthcare providers have a legal obligation to obtain informed consent from their patients prior to carrying out medical interventions. In consenting, patients autonomously authorise treatments or their participation in clinical research.

An individual's capacity for medical decision-making is not necessarily diachronically stable. It may, for instance, be affected by dementia, psychosis, intoxication, or high levels of stress (Department for Constitutional Affairs 2007). Some underlying causes are reversible, others are not. Besides certain illnesses, there are several types of medical interventions that have the potential to influence patients' decision-making. Classic examples are psychosurgery, psychotropic drugs, and certain forms of electrical brain stimulation. These interventions can have two types of effects: they may affect *whether* a patient has decision-making capacity; and—if the patient is decision-competent—they may exert an influence on *which* treatment option is ultimately selected. We will refer to the former as *threshold effects* and to the latter as *supra-threshold effects*.

Therapeutic interventions differ widely in the reversibility of these psychotropic modifications. Most effects of psychosurgery are permanent (O'Callaghan and Carroll 1982). Psychoactive drugs are on a wide spectrum, with half-lives ranging from a few hours to several weeks (Mauri et al. 2018). The focus of this article will be on electrical brain stimulation, and particularly on a subtype that can exert strong psychotropic influences, sometimes incidental to the therapeutic aim, while simultaneously being characterised by comparatively quick reversibility: deep brain stimulation (DBS).

We will argue that this rapid reversibility of psychotropic effects permits more fine-grained assessments of treatment preferences in patients who receive DBS. These challenge traditional procedures of medical decision-making, which do not consider the potential reversibility of threshold and supra-threshold effects and may thus produce unnecessarily inauthentic decisions.

While DBS seems best suited to enhancing patient autonomy in this way, we are calling for the reconsideration of decision-making procedures following *any* interventions that can have significant effects on capacity and decision-making when they share with DBS the characteristic of short-term reversibility.

We shall proceed as follows. To recapitulate what is required in medical decision-making, we will first review an exemplary legal framework governing capacity—the Mental Capacity Act from England and Wales. Next, we shall explain how DBS can, in some cases, influence patients' decision-making and illustrate the two types of effects that we have identified. We will then sketch how healthcare systems could incorporate these threshold and supra-threshold effects into their decision-making processes to realise a more granular procedure for establishing capacity. Doing so could strengthen the authenticity of treatment preferences in patients who undergo interventions with quick reversibility of psychotropic effects. Finally, we shall explore which professional obligations on healthcare personnel may flow from our considerations.

Legal frameworks of capacity

In England and Wales, the Mental Capacity Act 2005 stipulates that legal capacity to make decisions pertaining to one's own medical treatment is presumed for individuals over 16 years of age (Department for Constitutional Affairs 2005, S1(2) and S2(5)). If a person's legal capacity is challenged, the law specifies a two-stage enquiry.

The first stage, also known as the *functional test*, seeks to determine whether the patient is capable of making the decision in question. The required skills are outlined in Sect. 3(1): the patient must be able to understand the information pertinent to the decision, retain and weigh it, and communicate the decision. The functional test is applied to the patient's ability to make a *particular* decision. A patient may therefore have legal capacity to make a relatively straightforward decision but lack the capacity to make a more complicated one.

The second stage only applies if the patient is determined to be unable to make the decision. Its aim is to establish whether the inability is a result of an impairment in the functioning of the patient's mind or brain. The impairment does not have to result from a defined diagnosis, but the assessor must be satisfied that an abnormality in the mind or brain is the cause of the inability to decide.

Individuals who fail both tests are deemed to lack the legal capacity to make the decision in question. While patients' abilities to perform the above-mentioned tasks come in degrees, a threshold is needed for practical reasons (Meier et al. 2022; Beauchamp and Childress 2013). The law therefore collapses an individual's capacity status in relation to a particular decision to a binary form: patients either have or lack legal capacity to make the decision in question.

While not all jurisdictions use the exact same definition of legal capacity as England and Wales do, the issues we are raising in relation to DBS apply to all legal systems that distinguish between individuals who can and individuals who cannot make a decision. With this brief review of an exemplary legal framework in hand, let us now turn to the first of the two types of effects that DBS can have on medical decision-making.

Threshold effects

Three major types of medical interventions have the potential to influence patients' capacity to make informed decisions: psychotropic drugs, psychosurgery, and some forms of electrical brain stimulation. We will refer to the pushing of a patient above or below the threshold of capacity as *threshold effect*.

As already noted, we are focusing on a form of electrical brain stimulation that is administered by a permanently implanted neurostimulator: deep brain stimulation (DBS). The device, placed in a subcutaneous pocket in the chest, passes a current through electrodes implanted into subcortical structures of the brain. DBS is mostly employed for refractory movement disorders, such as Parkinson's disease (Deuschl et al. 2006) and dystonia (Fan et al. 2021), but appears to show promise also for patients with epilepsy (Zangiabadi et al. 2019) and Alzheimer's disease (Mello et al. 2025; Suthana and Fried 2014).

DBS-induced modifications can also positively influence patients' ability to make and express decisions, for example, by enabling communication through improvements in verbal memory and motor function (Mandarelli et al. 2018) that push them beyond the threshold of mental competence. However, negative effects on decision-making capability—most notably in conjunction with cognition and verbal fluency—have also been reported post implantation (Obeso et al. 2017; Wu et al. 2013). In one case, a previously competent patient's decline in decision-making ability upon the activation of the stimulator, which he had received for his Parkinson's disease, was so enormous that he had to be admitted to a psychiatric hospital. Consequently, available treatment strategies had to be discussed, and consent obtained, in the deactivated state, even though this entailed being under the influence of debilitating motor symptoms. Ultimately, the patient decided to have the stimulation activated again, to forgo decisional competence, and to spend his life at the psychiatric hospital to be relieved from his parkinsonism (Leentjens et al. 2004). Cases of this kind show that the presence of an *activated* deep brain stimulator should not automatically be regarded as the state most conducive to decision-making: threshold effects are bidirectional.

Hence, irrespective of whether an already implanted neurostimulator happens to be activated or deactivated when a patient is asked to give consent for a future medical intervention, yet deemed incapable to do so, a reversal of the device's state may reveal on/off-discrepancies that doctors can explore to enhance the patient's decisional capabilities.

While the exact mechanism of action is still unclear in DBS, it is hypothesised that the delivered current inhibits neurons surrounding the electrode in a way analogous to a lesion—only that this lesion is temporary (Grill et al. 2004). Since the current can be switched off at any point by deactivating the stimulator, (iatrogenic) effects on capacity are comparatively quickly reversible (Klaming and Haselager 2013; Mandat et al. 2006). Unlike in psychosurgery, the lesion is only active upon the ongoing delivery of a current; and unlike with psychotropic drugs, there is no need to wait until the respective substance has left the system.

This is not to say that the reversal of threshold effects is instantaneous in DBS. In some cases, there is still a transitory interval—sometimes referred to as the *washout period*—that can last up to a few hours (Cooper et al. 2013); nor does it mean that *all* effects are reversible. Scarring of neural tissue from the process of electrode insertion and from physicochemical interactions is likely to be irreversible (Vedam-Mai et al. 2018; Kozai et al. 2015). There may also be minor long-term neuroplastic or neurogenic changes (McKinnon et al. 2019; Ruge et al. 2014, 2011). Consequently, withdrawing the current (but leaving the device *in situ*) removes most of the modifying influences but does not return the affected neural tissue to its original state (Pugh 2019).

However, since the main effect of DBS is due to the actively delivered current—as is evidenced by the drastic fluctuations in symptoms that many patients experience in close temporal proximity to changes in the stimulatory patterns (Campbell et al. 2012; Mandat et al. 2006)—activation or deactivation of the device can in some cases reversibly influence a patient's ability to make a decision. In patients with implanted neurostimulators, a change in device state may therefore be tried in the hope of achieving a threshold effect, pushing the patient beyond the threshold of capacity for a particular medical decision, as illustrated by (fictional) Vignette 1:

> Margaret is a 52-year-old woman with epilepsy. Her epilepsy is refractory of pharmacological therapy, but it responds well to thalamic deep brain stimulation. When the stimulator is switched off, Margaret experiences seizures that make it difficult to fulfil the requirements of the decision-making test as set out in the Mental Capacity Act, particularly weighing and retaining relevant information, and particularly where the decision is complex. Ensuring that the device is switched on and functioning is a prerequisite to her capacity.

Attempting a change in a psychotropically relevant intervention with the aim of achieving a threshold effect is only *feasible* if the intervention is reversible, and it is only *practical* if the intervention is reversible both within an adequate time frame and without causing disproportionate side-effects. While DBS lends itself very well to this aim, this does not go for all other forms of treatments. In psychosurgery, targeted lesions are created in the brain, with the aim of alleviating the symptoms of mental disorders (O'Callaghan and Carroll 1982). Scarring and the removal of tissue are irreversible. Consequently, threshold effects cannot be achieved postoperatively.

Psychotropic drugs modify functions of the nervous system to induce altered cognition, perception, or mood (Julien et al. 2011). They exert their effects through chemical interactions with neuronal receptors. One and the same substance may, depending on the context, improve or attenuate a patient's capacity to make a medical decision. Opioids, for instance, can induce an acute confusional state that undermines a person's capacity; yet when administered to an individual in severe acute pain, the same substance may bring such relief as to enable them to pass both limbs of the capacity test (Sica et al. 2023). The administration or discontinuation of certain psychoactive substances may therefore permit patients to meet the legal threshold for capacity and make a decision—or cause them to fall below the threshold and be unable to make the decision.

Temporarily reversing the effects of psychoactive medication to test for threshold effects is not as straightforward as in DBS, where devices permit the instantaneous activation and deactivation of stimulation. Many of the standard drugs have long half-lives (Mauri et al. 2018). As procedures of obtaining consent must not impose overly burdensome requirements on healthcare personnel (Beauchamp and Childress 2013, p. 123), longer washout periods with extended waiting times would be impractical for transtemporal checks. However, in the case of short-acting substances, such as methylphenidate (Singh 2005), cross-checking should be considered—bearing in mind that the reversal of psychotropic effects may be only partial due to neuroplastic changes induced by the respective substance (Klein et al. 2024). Potential negative effects from the temporary discontinuation, like withdrawal syndromes, must also be taken into account (Brandt et al. 2020).

Supra-threshold effects

By the addition or the subtraction of substances or electrical stimulation, individuals who have capacity may also come to reach *different* decisions (Maslen et al. 2015; Mandat et al. 2006). In such cases, the drug or the device is not affecting legal capacity per se, but it is influencing the attitude individuals display towards choices. In this paper, we are interested in the significance of this effect for decisions regarding patients' future treatment options. We shall refer to the influence of ongoing psychotropically relevant interventions on the choices made by patients who have capacity as *supra-threshold effects.*

A key dimension that differentiates treatment options is the associated risk (Boeri et al. 2018). Not only can the intended or unintended stimulation of certain pathways, for instance of the dopaminergic, directly affect neuronal risk processing (Schultz 2015); risk tolerance is also susceptible to mood (Young et al. 2024), which is a parameter that DBS often modifies (Meier 2023; Zuk et al. 2022). Vignette 2 illustrates how DBS can exert such a supra-threshold effect:

> Ruth has a deep brain stimulator implanted to treat her Parkinson's disease. The electrodes apply a modifiable current that improves her motor symptoms. Unfortunately, the device—when activated—has detrimental effects on Ruth's mood. Ruth has recently been diagnosed with bowel cancer, and the general surgeons have advised her of two treatment options. One is simpler, involving the formation of a stoma. It would improve her quality of life but would not remove the cancer. The second option is a more challenging procedure, involving an attempt to excise the malignancy, clear any affected lymph nodes, and potentially rejoin the two ends of intestine.
>
> Ruth meets with the surgical team to discuss the two options. With the device activated, she is able to pass both of the legal tests for capacity in relation to the two decisions. However, with the device switched on, Ruth's mood is low and she is less willing to endure the more complex but potentially life-prolonging operation. She is pessimistic and although she fully understands her options, she does not consider the associated risks to be acceptable nor the recovery from the more prolonged procedure tolerable.
>
> Concerned about the potential psychological impact of her neurostimulator, Ruth attends the second consultation with the device switched off. The surgical team find that she still has capacity to make the decision, that is, that there is no on/off-discrepancy: irrespective of the stimulator's state, Ruth can understand, retain, and weigh relevant information and communicate her deci-

sion. However, with the device deactivated, her mood is improved and she feels more confident about managing the more invasive option.

In this fictional case, the key aspect that DBS influences is Ruth’s perception of risk versus the potential therapeutic benefit, causing the selection of treatment options to depend on whether the stimulator is active or inactive. Changes in *risk aversion* have indeed been observed in patients who receive DBS for Parkinson’s disease (Voon et al. 2024).

However, DBS may also affect other relevant psychological parameters. There is evidence that the stimulation can change patients’ *cognitive* parameters, modifying the number of factors that they are able to consider or the level of detail with which the factors can be evaluated (Runia et al. 2023; Zangaglia et al. 2009). The speed at which information processing takes place can also be affected (Frank et al. 2007). Further, DBS may change the nature of *patient–clinician interactions*, partly due to effects on verbal fluency (Zangaglia et al. 2009), so that patients may end up being provided with different information, not least because improved disease management allows them to be more engaged with their consultation (Thomson et al. 2023). Fluctuations in patients’ *emotional* state, which may influence their enthusiasm for considering information or their willingness to entertain certain options, have also been found (Lewis et al. 2015).

There is, consequently, an on/off-discrepancy also for *supra*-threshold effects: DBS patients with capacity may—by reverting the state of their devices—come to different decisions regarding treatment plans. Naturally, medication can have comparable effects on mood (Carhart-Harris et al. 2021; Fleishmann and Kaliski 2017), attention (Cortese 2020), and cognition (Chen et al. 2022)—and thus also on decision-making. As noted above, DBS differs from many psychoactive substances in that most of the effects that the stimulation induces are comparatively quickly reversible. For short-acting substances, however, carrying out transtemporal cross-checks can be equally feasible and should be considered. Thus, short-term reversibility calls for consent procedures that take into account on/off-discrepancies to increase the authenticity of decisions taken under the influence of psychotropic interventions. How could this be achieved?

Cross-checking for threshold and supra-threshold on/off-discrepancies

The Mental Capacity Act provides that unless there is evidence to the contrary, everyone over the age of 16 is presumed to have capacity (Department for Constitutional Affairs 2005, S1(2) and S2(5)). Consequently, no further enquiry into the presence, state, or mode of an implanted neurostimulator is usually necessary.

When a clinician has reason to believe that a patient may not have capacity, they would normally follow the procedures of the Mental Capacity Act, as outlined above. However, we suggest that when a patient receiving DBS is deemed to lack capacity, the stimulator’s state be changed at least once: to *off* if it was previously active; and to *on* if it was initially deactivated. The Mental Capacity Act requires that all practicable steps should be taken that may enable patients to exercise their decision-

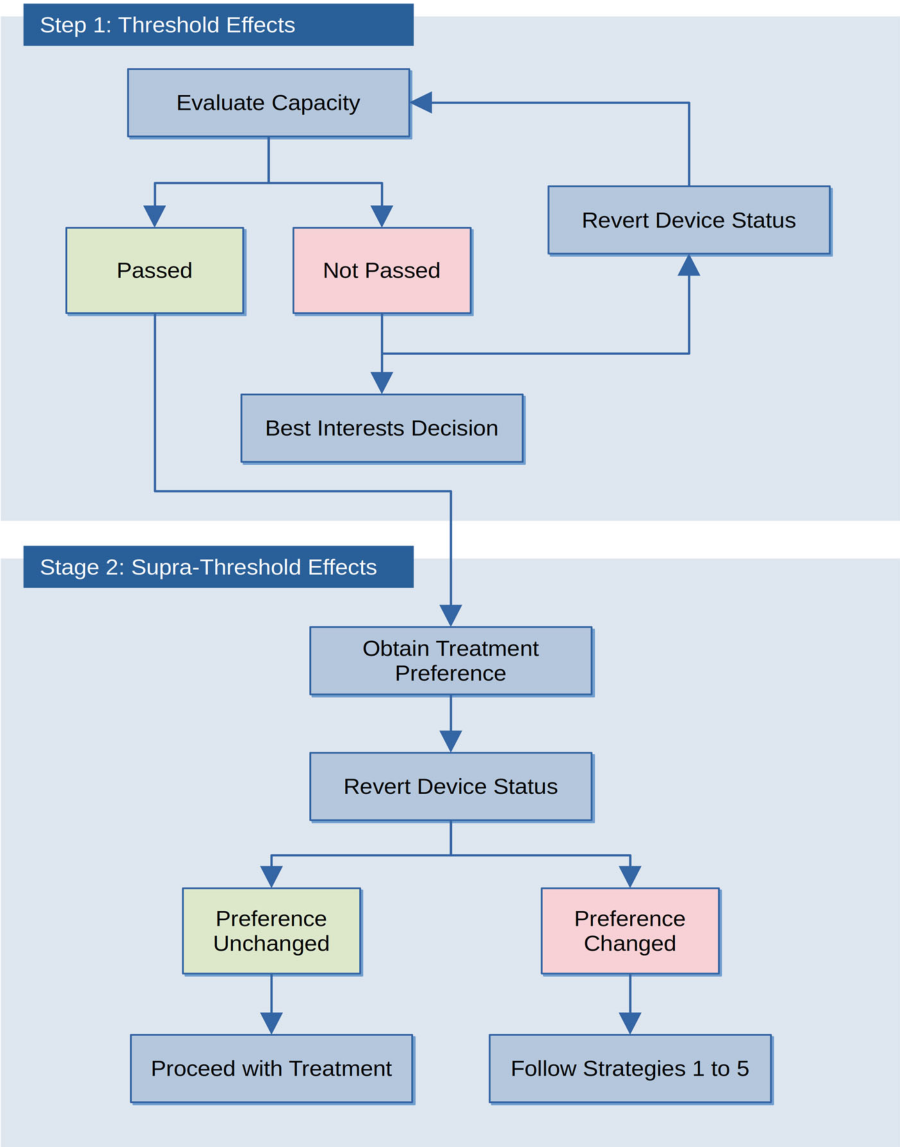

Fig. 1 Cross-checking procedures for threshold and supra-threshold effects

making capacity (Department for Constitutional Affairs 2005, S1(3)). Hence, when changing the state of the device could potentially enable a patient to have capacity, when there is a chance—however slim—that the reversal may exert a *threshold effect*, this attempt should be made.

Where changing the state of the device enables a patient to have capacity in relation to a particular decision, or where capacity remains unchallenged to begin with, DBS may nevertheless affect which treatment option the patient ends up selecting—that is, it may exert a *supra-threshold effect*. We therefore propose that in this case, too, the clinician carry out a cross-check by offering to put the stimulator in a different mode to determine whether the patient still offers the same decision (Fig. 1).

The interval to be observed between the attempts will depend on the washout period of the device's influence (if previously activated) or the time span required for the stimulation to take effect (if previously deactivated). These, in turn, appear to be contingent mainly on electrode location and differ slightly between subjects (Cooper et al. 2011).

As mentioned earlier, DBS can also have minor structural effects that are not reversible quickly enough for such a test to be reasonably applied to them—such as neurogenesis—and even effects that are permanent—such as scarring (Ruge et al. 2014). However, most psychotropic modifications are contingent on the ongoing delivery of a current. One can therefore expect cross-checks to be quite revealing in certain DBS patients. This is in contrast to other forms of neurostimulation, like electroconvulsive therapy (ECT) or transcranial magnetic stimulation (TMS), where the induced effects persist for longer intervals post intervention (Ousdal et al. 2022). In these modalities, transtemporal cross-checks would be impracticable.

When a cross-check yields identical treatment preferences, there is no need for further investigation. When it reveals a *supra-threshold on/off-discrepancy*, however, one must decide which preference to follow. There are, we shall propose, five different ways of proceeding: (1) prioritising the preference obtained when the device is in the *regular state* for the patient; (2) prioritising the *latest* decision obtainable; (3) prioritising the *earliest* decision obtainable; (4) *confronting* the patient with the justification they provided in the opposite device state; (5) *redesigning*, if possible, the treatment offers until the on/off-discrepancy can be eliminated. We will now consider these strategies in more detail.

Strategy 1: the regular device state

If the device is usually activated, this is the preference expressed when it is switched on. If the stimulation is usually deactivated, it is the preference expressed when the device is switched off. The goal of this strategy is obtaining a decision in the state in which the patient has spent the majority of their time, so that it would reflect best the preferences that obtain most of the time. The patient will likely be in this state during the initial exploration of a treatment plan and between consultations, when considering the options. The fact that the decision is obtained under the patient's ordinary living conditions confers a particular priority on choices made in this device state. Predictively, post-intervention acceptance of pre-intervention decisions and their respective consequences are going to be greatest when both events occur under the same stimulatory parameters.

The weakness of Strategy 1 lies in the assumption that the patient also *will* be spending most of their time in the selected device state after the planned intervention has taken place. In patients whose stimulator is usually active, preferences that might predate the implantation of the device could resurface once its influence changes—for example, if the stimulation had to be reduced at a future point in time.

Conversely, in patients whose device is usually deactivated, novel preferences could form if their medical condition required more aggressive stimulation. Strategy 1 takes into account neither of these scenarios.

Strategy 2: the latest decision

Counting the latest decision as the decisive one promises to achieve the greatest temporal correspondence between the point in time at which the decision is made and the moment it is carried out in the form of the medical intervention that was selected. Usually, this strategy should also provide the patient with the maximum time for reflection, enabling them to take into consideration additional medical evidence and opinions that may not have been available at any previous point. This is indeed how decision-making often works in clinical practice: patients may revise their choices several times until, often somewhat arbitrarily, the most recent decision is deemed the decisive one.

However, if the exploratory and diagnostic processes necessitate changes in the stimulatory parameters, the patient may end up having spent only a fraction of their time in the very state in which the decision is finally made, which can reduce the diachronic stability of the decision. For the same reason, Strategy 2 is also less suited for patients whose conditions require the frequent adaptation of stimulatory settings. Counting the latest decision is relying a snapshot, not on a mean.

Strategy 3: the earliest decision

The law as it stands gives priority to the most recent decision, in that a patient with capacity cannot be bound by a previous decision made with capacity. Allowing a prior decision to take precedence over the latest one would thus require a new legal mechanism. This strategy will often, but not always, coincide with the first one as the earliest consultation during which a decision could be obtained will ordinarily be held in the patient's usual device state.

Strategy 3 has the disadvantage of the moment at which treatment for the newly occurring disorder is sought—and the first decision is made—being arbitrary vis-à-vis the DBS-related parameters that might exert the supra-threshold on/off-discrepancies in question. Additionally, and in contrast with Strategy 2, patients will have had the least possible amount of time for taking into account additional information and reason with it. If authenticity is construed as diachronic stability of an individual's decision, pursuing such a strategy can be problematic.

Strategy 4: confrontation with the opposite device state

If one regards picking any one particular point in time as too arbitrary to capture effects that unfold transtemporally, one may instead attempt to put the reasoning elicited in one device state in touch with that obtained in another. The hope would be reaching a kind of intrapersonal agreement on the best course of action. Since the patient cannot be consulted with the device activated and deactivated at the same time, Strategy 4 is an asynchronous approach: first, the patient is asked not only for their decision but also to provide justification for why they prefer the selected course of action over the available alternatives. Their reasoning is recorded verbatim. Then, after an adequate washout period has been observed (or, if the device was previously deactivated, when the stimulation has taken effect), the patient is requested to decide again and give justification a second time, under otherwise identical conditions. Only after this step has been completed is the patient confronted with the reasoning previously obtained and asked whether their current preferences might change in the light of engaging with their earlier decision and justification.

As DBS delivered to most areas of the brain is not known to affect memory, the recording of the patient's justification is not predominantly meant to replace their own recollection of their prior response, to which they usually still have access. Rather, the intention is to present the patient with their former reasoning process in the most neutral form possible, to make transparent the psychotropic effects of DBS described in the foregoing section. However, there will be limits to the success of this method: from their first-personal perspective, subjects are often not able to separate the effects of ongoing electrical stimulation from their own—unmodified—reasoning; rather, the two are seamlessly integrated into a seemingly coherent narrative leading up to the decision that is ultimately taken (Heinrichs 2012; Delgado 1969).

The possession of memories of the first attempt at providing justification also points to another difficulty: although those memories, when being recalled, might now appear to the patient in a different emotional hue due to the reversal of the device state, their very existence implies that switching the stimulation on or off can never fully return an individual to a previous condition. Any experiences had in the interval between the reversals can, and likely will, exert some kind of influence on the second decisional outcome.

Strategy 4 is further complicated by another problem. Unless one is prepared to give priority to one device state interpreting the reasoning of the other (in which case one is, in a sense, faced with the very dilemma that makes deciding between Strategies 2 and 3 so difficult), one would have to revert the device yet another time to give the patient the opportunity to reassess their second justification also before the background of their initial device state. Should the patient, after having undergone this double cross-check, still offer diverging decisions, there would be no neutral first-personal viewpoint from which they could evaluate the recorded justifications in an impartial way, as the patient will always be either under the influence of DBS or not.

Could the clinician provide this viewpoint from the third-personal perspective, evaluating each set of preferences for congruence with the patient's overall narrative? According to narrative-identity theory, individuals integrate their values and preferences into an internalised life story that, evolving transtemporarily, gives meaning and a unifying frame to their existence (Schechtman 2007). Personal narratives strive for internal coherence, be it chronological, thematic, or causal. Consequently, incongruences should in principle also be detectable from a third-personal point of view.

Several authors have indeed suggested relying on narrative-identity theories in conjunction with neurointerventions (Leuenberger 2021; Goering et al. 2017; Gilbert

2015; DeGrazia 2005). While exploring patients' narrative identities is undoubtedly helpful for conceptualising some of the induced psychological modifications, there are two complications when employed in the way envisioned in this paper: firstly, as mentioned earlier, DBS often operates below the level of conscious awareness, so that patients would not always be able to articulate or even grasp the modifying effects of the neurostimulation that they are receiving (Pugh 2020). Secondly, it is questionable whether clinicians would be in a position to adequately interpret and weigh any disruptions in the patient's narrative. Spotting the more subtle modifications requires substantial familiarity with an individual's personal background and life story, which cannot be presupposed in most clinical settings. Involving yet another party, like a relative who knows the patient well, would facilitate this endeavour. Doing so, however, could introduce further variables into the decision-making process and would—itself—require consent on the part of the decision-competent patient (Schmitz-Luhn et al. 2012).

While the sketched exploratory process is likely to improve the patient's understanding of the implications of the treatment in both device states and could thus strengthen the diachronic stability of their decision-making, this way of proceeding would come with excessive demands on clinicians' time as the process of deliberation would involve not only the faithful recording of preferences and their careful cross-examination but also the observation of adequate washout intervals between the consultations. In exchange, however, Strategy 4 would presumably yield the most fine-grained assessment.

Strategy 5: redesigning of treatment offers

The goal of the fifth strategy is to sidestep the difficulties noted so far by eliminating on/off-discrepancies altogether—not by changing DBS parameters but by modifying the different treatment plans offered to the patient until reverting the device state no longer results in different plans being chosen. Arriving at an option that the patient picks consistently irrespective of whether they are receiving neurostimulation is inherently desirable. Unfortunately, however, selecting Strategy 5 will not always be feasible. Available forms of treatment are naturally constrained by a multitude of factors, so that one cannot simply amend them at will. Moreover, there is no guarantee that the remaining differences between them will indeed not trigger a supra-threshold effect in any given individual—especially since the treatment courses offered must still vary in relevant aspects, so that the patient remains in the driver's seat, rather than only being able to formally consent to what is basically a single premeditated plan.

When going with Strategy 5, two conflicting aims must therefore be balanced very carefully: achieving diachronic decisional stability by way of eliminating supra-threshold effects and preserving a sufficient breadth of the decisional space still available to the patient. Depending on the specific situation, the latter goal can be even more important than the former. If the decisional space is found to be shrinking substantially until supra-threshold effects can be stabilised, honouring patient autonomy may dictate resorting to another strategy instead.

Authenticity under the influence of DBS

Which of the five strategies should clinicians pursue? Which would be superior at eliciting authentic preferences? And what does 'authentic' even mean in this context? Traditionally, preferences are regarded as authentic when they are a function of an individual's internal, self-determined reasons and goals rather than a product (predominantly) of external factors (Rousseau 1992). Extracted preferences and decisions should therefore reflect what philosophers have termed the 'authentic self': an individual's core, or essence, that is taken to remain diachronically stable (Guignon 2008).

However, not only is there a great variety of conceptions of authenticity, all differing in significant aspects (Dworkin 1988; Frankfurt 1971; Fromm 1946; Heidegger 2006; Kierkegaard 1992; Nietzsche 1953; Sartre 1966), including some that reject the notion of authentic selves altogether (Feldman 2015; Bialystok 2014). DBS also adds an additional layer of complexity that most accounts are not well prepared to handle: due to the stimulator being implanted, this initially external source of influence can, over time, come to form part of an individual's identity, which blurs the traditional internal/external distinction. Strategy 1, for instance, aims at attaining congruence between past preferences and their future realisation by prioritising the preference obtained when the device is in its regular state; but whether this congruence manifests under the influence of an activated or deactivated device is immaterial. Still, the neurostimulator *must* be in one determinate state at the moment at which consent is obtained, which forces a choice on the clinician. In DBS patients, one can therefore not indiscriminately equate authenticity with the absence or minimisation of this prima facie external interference. Authentic preferences may sometimes be exactly those uttered under such influence.

Recognising any one strategy as *generally* superior is difficult without simultaneously subscribing to one of the many rivalling conceptions of authenticity, endorsing a particular model of the self, and favouring a certain view of diachronic persistence—philosophical debates of which we resolved to stay clear for the purpose of this paper. Procedural reasons, such as constraints on the time and effort that healthcare systems can allocate to obtaining consent, are also going to play a role. These factors would gain additional weight if, along with merely activating or deactivating the device, healthcare professionals were also to engage in the time-consuming process of experimenting with stimulation parameters—amplitude, frequency, and pulse width—to facilitate decision-making.

The—more modest—intent of this article, besides defining the problem, is to formulate the basic practical options available to clinicians, together with what we regard as their respective virtues and vices, to provide a basis for further discussion. Presently, procedures for obtaining consent largely ignore the existence of suprathreshold on/off-discrepancies. More pressing than singling out the most promising strategy is integrating cross-checks into medical decision-making under the influence of interventions with quickly reversible psychotropic effects in the first place.

Obligations of healthcare professionals

We shall end by exploring which obligations of healthcare professionals may flow from our considerations. Besides the legal framework, healthcare workers checking capacity must normally adhere to professional codes of conduct. In the UK, for example, the General Medical Council's guideline *Decision-Making and Consent* requires of registered practitioners that they inform patients of the benefits, risks, and uncertainties of treatment options (General Medical Council 2020, § 10). One may interpret this as requiring them also to notify patients that DBS has the potential to influence their future decision-making.

There are at least two points at which this information may need to be disclosed. First, when obtaining consent for the stimulator's *initial implantation*, as being aware of possible psychotropic influences is material to deciding whether to go ahead with the surgery; and a second time whenever consent for any *subsequent procedure* is being obtained, given that the device state could contribute to shaping the decisional outcome in the described ways.

Paragraph 18 of *Decision-Making and Consent* requires clinicians to find out about patients' needs, values, and priorities that may influence their decision-making (General Medical Council 2020). This may reasonably include highlighting that neurostimulators can sometimes alter mood or cognition and that one way to identify such on/off-discrepancies is to deactivate the device temporarily.

Although the long-term effects of DBS are only poorly understood, it is conceivable that initially fully reversible modifications can, after a prolonged interval of stimulation of a currently unknown length, become permanent or may at least no longer be fully reversible (Ruge et al. 2014). An important—and, as we have been arguing, instrumentally useful—characteristic of DBS is that its deactivation enables patients in whom on/off-discrepancies occur to revert to the pre-implantation state in relation to neuropsychiatric alterations (with the exception of immediately permanent structural effects like scarring, as detailed above). Where accumulated time spent under the influence of DBS threatens to limit patients' future ability to access this fallback option, and thus the performance of cross-checks, patients should be informed also of this possible long-term consequence. After all, giving consent normally also implies one's ability to withdraw it again (Heinrichs 2012).

Clinicians should also be aware of the fact that the suggested cross-checks are less well suited for the (currently small) group of cases in which DBS is not employed to mitigate predominantly physical ailments like tremors—where neuropsychiatric modifications occur as side-effects—but where stimulators were implanted with the specific aim of treating psychiatric disorders (Sheth et al. 2022; Baldermann et al. 2021). The risk of reverting patients to states that can cause extreme distress or in which they could pose a danger to themselves or to others must be balanced against the expected gains in relation to decision-making.

We would also like to emphasise that for patients who have capacity, the legal and professional obligations could only ever authorise clinicians to inform, discuss, and recommend. A clinician could not insist that decisionally competent patients adjust any settings of their neurostimulators. As supra-threshold effects do not (by definition) impair capacity, it should be open to patients to refuse to modify their device without prejudicing their right to decide on a treatment plan.

The legal and professional requirement to presume capacity is paramount. Consequently, the mere presence of a neurostimulator is not sufficient to rebut the presumption of capacity for an adult patient. A standard presumption to the contrary would put the autonomy of this patient group at risk. This is in line with assessing capacity under the effects of pharmacological therapies, where the use of a particular prescribed psychoactive substance does not automatically rebut the presumption of capacity either (Department for Constitutional Affairs 2007).

Conclusion

We advanced five main claims: (I) The effects of deep brain stimulation (DBS) may move some patients beyond or below the threshold commonly set for deeming them capable to make a particular treatment decision. We called these *threshold effects*. (II) DBS may also influence *which* treatment option a patient with capacity selects, depending—among other factors—on whether the device is switched on or off while consent is being obtained. We called these *supra-threshold effects*. (III) Whenever a medical procedure is considered for a patient with an implanted neurostimulator, the consent process should take account of both types of effects: in patients who do not meet the capacity threshold, the device state should be reverted in the hope that this has a positive influence on their capacity. In patients who have capacity, cross-checks should flank the decision-making process to screen for potential supra-threshold effects. (IV) If on/off-discrepancies are found, there are five ways of dealing with the conflicting choices: prioritising the preference obtained when the device is in its *regular state,* prioritising the *latest* decision, prioritising the *earliest* decision, *confronting* the patient with reasons they provided in the opposite device state, and *redesigning* the treatment offers until the on/off-discrepancy can be eliminated. (V) Professional obligations of healthcare personnel demand that patients who receive interventions that have the potential to exert future threshold or supra-threshold effects be informed about this possibility—first when obtaining consent for the initial implantation of the stimulator and a second time whenever the ongoing stimulation might be affecting a subsequent instance of medical decision-making.

We argued that, due to the short-term reversibility of most effects, DBS lends itself especially well to decision-making procedures that take into account on/off-discrepancies. However, this approach should also be considered for other medical interventions with the potential to induce threshold effects—if their psychotropic influences can be reversed within clinically reasonable time frames and if the side-effects of the temporary withdrawal are tolerable. This includes drugs with short half-lives. Wherever threshold or supra-threshold effects can be utilised at comparatively low cost to the involved parties, one should do so to strengthen the authenticity of medical choices and enhance patient autonomy in decision-making.

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Declarations

Conflict of interest L.J. Meier and A. D'Sa declare that they have no competing interests.

Ethical standards For this article no studies with human participants or animals were performed by any of the authors. All studies mentioned were in accordance with the ethical standards indicated in each case.

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