Ethical Issues in the Decision Making Process of Paediatric Deep Brain Stimulation

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Vt 2014
Masteruppsats, 30 hp
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Abstract

Deep Brain Stimulation (DBS) är en form av behandlingsmetod där elektroder implanteras i patientens hjärna, och där sedan en svag ström skickas via elektroderna till utvalda delar av hjärnan för att kompensera för neurologisk dysfunktion. Denna behandlingsmetod används främst för motoriska sjukdomar såsom Parkinsons sjukdom och dystoni, men har på senare år även börjat användas för att behandla vissa psykiatiska sjukdomar såsom Tourettes syndrom, depression och OCD-störningar. Många av sjukdomarna som behandlas med denna metod uppdagas hos patienten i ung ålder, och förvärras med åren. Röster har därför höjts för att påbörja behandling av sjukdomarna i ett tidigt skede, men behandlingsmetodens invasiva karaktär, samt behandlingsområdets känslighet, har lett till en diskussion kring hur beslutfattningsprocessen gällande DBS-behandling av barn bör utformas. I denna uppsats presenterar jag de vanligaste positionerna i denna diskussion, men finner dem otillräckliga då de inte i tillräckligt hög grad tar hänsyn till variationsgraden av autonomi inom patientgruppen. Jag presenterar därefter ett schema för hur beslutfattningsprocessen bör utformas så att hänsyn tas till patientens grad av autonomi. Jag analyserar också de värden som jag anser skall vägas in, och hur de står i relation till varandra, när det kommer till att fatta beslut rörande DBS-behandlingar av barn.
1. Introduction

Deep brain stimulation (DBS) is a therapeutic method, where a “pacemaker for the brain” is inserted in the patient. The device sends electrical pulses through electrodes to specific parts of the patient’s brain, in order to compensate for neurological dysfunction. DBS has been used for decades as a final resort treatment for patients suffering from Parkinson’s disease. But as the technology has evolved, the research has moved forward, and the body of clinical experience has grown. The method is today used to treat several disorders, including depression, dystonia and essential tremor, and experimental treatments have been reported concerning Tourette’s, anorexia, epilepsy, Alzheimer’s, et cetera.¹

Although the ethical debate surrounding DBS has increased in recent years, its main focus has been on ethical questions concerning adults possessing medical competence.² There is however very little written on the subject of paediatric DBS, although there are none the less important ethical issues that need to be discussed.³ Recognizing this, Lipsman et al writes:

We propose that strict ethical guidelines and criteria be employed prior to any DBS application in the pediatric age-group. Strict attention needs to be given to the informed consent process, and to a comprehensive discussion of the risks, benefits, and treatment expectations and goals.⁴

As it is, the proposal of Lipsman and colleagues has yet to be realized. Today, paediatric DBS is performed in clinics all over the world, even though no clear ethical guidelines specific for paediatric populations have been developed. Yet, it is commonly thought that the invasiveness of the procedure calls for such specific guidelines, over and beyond the general guidelines for paediatric health care.⁵ The ethical issues involved in paediatric DBS are therefore in urgent need of analysis and assessment. Generally, it is suggested that we in the decision making process of paediatric DBS apply either a protectionist

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¹ V. Johansson, 2013
² V. Johansson, 2013; F. Focquaert, 2013
⁴ N. Lipsman et al, 2010. p. 5
⁵ C. Woopen et al, 2013; F. Focquaert, 2013
approach, a liberalistic approach, or a shared decision approach. A not uncommon standpoint among clinicians seems to be that we simply ought to judge case-by-case. The aim of this paper is to provide an ethical analysis of the decision making process of paediatric DBS, and propose a procedure that is sensitive the patients’ level of autonomy, and yet more guiding than just stating that we have to judge case-by-case.

In chapter 2 I explain what DBS is and I briefly go through the method’s past and present, and predictions of its future. I will also in this chapter provide an overview of the DBS research and practise done in paediatric populations so far. In chapter 3 I provide an overview of “what is at stake” in paediatric DBS. This includes weighing the risks and benefits of DBS interventions in paediatric patients (3.1), and analysing the core concepts of Quality of Life (3.2) and An open future (3.3). In chapter 4 I assess and analyse the structure of the decision making processes concerning paediatric DBS. This is done through an assessment of the concepts of Autonomy and Decisiveness, and how they connect in the context of paediatric DBS in (4.1). In (4.2) I present my proposal on how the decision making process of paediatric DBS ought to be structured. In (4.3) I explore the responsibilities in the informed consent process, and in (4.4) I present guidelines for how to act in the best interest of the child.

2. Deep Brain Stimulation

2.1. The Past, the Present, and the Future of DBS
Using electricity to treat disease and malfunction in the human nervous system is no new method – almost two thousand years ago it was used for treating pain. However, the term Deep Brain Stimulation has since the 1970’s referred to the electronic systems developed and trademarked by Medtronic. Robert Coffey defines the term as follows:

Deep brain stimulation (DBS) is the application of implantable electrical

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6 L. Ross, 2004 ; L. Hagger, 2009 ; F. Focquaert, 2013
7 Fish of the Torpedinidae family were at this time used for medical purposes because of their ability to generate electricity. H. Fodstad, M. Hariz, 2007
8 M. Hariz, P. Blomstedt, L. Zrinzo, 2013
stimulation technology and devices to treat neurological disorders. [...] DBS — targeted to particular brain nuclei or pathways that are specific for the disorder under treatment — influences brain function and behavior (movements, sensations, and/or thoughts and feelings) in ways that can relieve symptoms and improve the overall functioning of the patient. Depending upon the particular disorder, target site in the brain, and stimulation parameters being administered, DBS may exert excitatory (facilitate neural conduction or activity) or inhibitory (block neuronal activity or conduction) effects — sometimes discussed under the broad term “neuromodulation.”

When using the term 'DBS', I shall henceforth refer to the therapeutic method as described above by Coffey, unless another description is explicitly referred to. When performing the procedure, an electrode is implanted in the patient’s cranium, running through the cerebral membrane, and into the part of the brain targeted for the specific intervention. A cable is placed under the skin, running from the electrode on top of the patient’s head, to a pacemaker that is placed in a “pocket” under the skin of the patient, usually under the left collarbone. The pacemaker is then adjusted to send an electric pulse of optimal strength to the target area in the patient’s brain. The strength of the pulse can later be managed by holding a radio transmitter next to the pacemaker. The battery of the pacemaker is changed every 3 – 7 years, depending on the level of stimulation. If the patient so wishes, the device can be shut off, and the effects of the stimulation then cease.

In the 1970’s and -80’s, the main symptoms targeted using DBS were the very same as those targeted two thousand years earlier: pains. The success was at this time very limited, but researchers and clinicians saw potential in the method, and started exploring its possibilities by applying it in treatment of other medical conditions. In the late 80’s, positive results started to come back from trials using DBS in treatments of involuntary movement disorders.

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9 R. Coffey, 2009 p. 208
10 Picture from: ST Dystonia.
such as essential tremor, Parkinsonian tremor, Parkinson’s disease, and some forms of dystonia.\textsuperscript{11}

To this day, these conditions are still the ones most commonly treated using DBS, and the procedure is well established as a last resort treatment for movement disorders of this kind, as well as for some forms of chronic pain.\textsuperscript{12} However, medical trials are being conducted in treatments of other conditions, including psychiatric disorders such as Tourette’s syndrome,\textsuperscript{13} epilepsy, \textsuperscript{14} depression, \textsuperscript{15} obsessive-compulsive disorders (OCDs), \textsuperscript{16} Alzheimer’s syndrome,\textsuperscript{17} drug addiction,\textsuperscript{18} and autism\textsuperscript{19} – all with positive results.

Now, with the knowledge of human neurology rapidly growing, and more refined medical technologies emerging, the future of DBS is looking bright. In addition to making established procedures like treatment of tremor, dystonia, and Parkinson’s disease safer, easier, and more exact, and exploring the effects of DBS in the psychiatric disorders mentioned above further, hopes are that the method can be developed to be used effectively in treatments of further conditions in the future. Studies indicate possible success in using DBS to treat eating disorders,\textsuperscript{20} post-traumatic stress disorder and post-traumatic minimally conscious state, bipolar disorder, tinnitus, and to regulate respiration, blood pressure and heart rhythm.\textsuperscript{21} It has also been indicated that DBS could be used to treat cognitive\textsuperscript{22} and anti-social disorders.\textsuperscript{23}

\textbf{2.2. Paediatric DBS – Research and Practice}

Although DBS has become an established and well-documented therapeutic method for treating dystonia, Parkinson’s disease and tremor in adults, the

\begin{itemize}
\item \textsuperscript{11} Ibid.
\item \textsuperscript{12} P. Blomstedt et al, 2013
\item \textsuperscript{13} M. Hariz, M. Robertson, 2010 ; J. Houeto et al, 2004
\item \textsuperscript{14} P. Boon et al, 2007 ; K. Vonck et al, 2013
\item \textsuperscript{15} P. Blomstedt et al, 2011 ; H. Mayberg et al, 2010
\item \textsuperscript{16} B. Greenberg et al, 2006 ; L. Gabriëls et al, 2003
\item \textsuperscript{17} A. Laxton et al, 2010 ; G. Smith et al. 2012
\item \textsuperscript{18} CE Valencia-Alfonso et al, 2012 ; R. Pierce, F Vassoler, 2013 ; J. Voges et al, 2012
\item \textsuperscript{19} V. Sturm et al, 2013
\item \textsuperscript{20} H. Wu et al, 2012 ; N. Lipsman et al, 2013 ; D. Whiting et al, 2013
\item \textsuperscript{21} P. Blomstedt et al, 2013
\item \textsuperscript{22} H. Freund et al, 2009 ; P. Barnikol et al, 2010
\item \textsuperscript{23} M. Funagalli, A. Priori, 2012
\end{itemize}
research, practise and documentation of treating paediatric populations is rather limited. The number of paediatric patients receiving DBS is relatively low, compared to adult populations, and the support for studies documenting the effects of DBS over time in paediatric populations is rather scarce.\textsuperscript{24} To complicate things further, most centres that perform paediatric DBS do so without distinguishing between adult and paediatric interventions when reporting.\textsuperscript{25} This not only makes it difficult to know how many children have been treated with DBS, but it also makes it difficult to do follow-ups specific to the paediatric populations. However, there are some studies published on the efficiency of paediatric DBS, especially regarding dystonia, that report success in medical procedure as well as in improving quality of life of the patient – even if the physical effects sometimes have been limited.\textsuperscript{26} Some studies have also been done on the success rate in adult populations compared to paediatric ditto. C. Woopen et al writes:

Whereas some studies did not find a correlation between age at onset or age at surgery and outcome (Holloway et al., 2006), another study demonstrated that patients with primary dystonia older than 21 years at surgery improved less than patients younger than 21 years (Isaias et al., 2008). Similar findings were reported for patients with dyskinetic cerebral palsy (CP) after GPi-DBS. The younger group (<16 years) responded far better than the older group (Marks et al., 2011). In summary, there is evidence that early initiation of GPi-DBS may be beneficial both in DYT1-positive dystonia, as well as in dyskinetic CP.\textsuperscript{27}

Thus, there is some evidence that DBS surgery, in patients with DYT1-positive dystonia or dyskinetic CP, performed early in life increases the improvement rate of the patients’ conditions.\textsuperscript{28} It has also been shown that, so far, the

\begin{itemize}
\item \textsuperscript{24} C. Woopen et al, 2013
\item \textsuperscript{25} N. Lipsman et al, 2010
\item \textsuperscript{26} E. Air et al 2011 ; H. Gimeno et al, 2012 ; C. Lundy et al, 2009
\item \textsuperscript{27} C. Woopen et al, 2013, p 83
\item \textsuperscript{28} Woopen et al also speculate that: "The effect of DBS at an early stage of development might be superior compared to patients who are operated during adulthood in terms of learning and relearning motor tasks. Motor skills are probably important in all aspects of development, including cognitive function and social interactions. Children explore the world to learn about it. Patients who have not had normal function since early development require reversal of maladaptive changes and functional or structural changes (Eltahawy et al., 2004). One might therefore speculate that longstanding aberrant neural plasticity limits the effect of DBS and,
improvement rates are lower in paediatric populations where the condition is more severe, meaning that patients respond better to DBS if they are less affected by their condition (patients with very severe conditions, where the improvement rate is estimated to be lower than 20%, are referred to as “non-responders”).  

Indications like these have caused many writers to urge treatment of patients suffering from movement disorders early in life.

While the support for studies concerning the effects of DBS in paediatric populations is overall scarce, the support for studies concerning DBS in psychiatric treatments in paediatric populations is extremely rare. Although there are a few case reports on successful DBS treatments of adolescents in ages 16 – 17, reports on DBS treatments of younger children are more difficult to find. However, discussions have been initiated regarding whether it is ethically justifiable to not offer DBS for psychiatric disorders to paediatric patients.

3. The Stakes: Benefit, Harm, and the Interest of the Child

Given the pace of technological progress and the accumulation of clinical experience, questions do arise concerning the ethics of not offering paediatric populations an effective method for treating many movement- and psychiatric disorders. In this chapter, I will present and discuss some of the most important issues that are at stake in paediatric DBS for movement- and psychiatric disorders. In the first subsection 3.1, I discuss the risks and benefits of using DBS in comparison to using other methods (pharmaceutical therapies, alternative neurosurgical therapies). This discussion eventually lands in the widely used – but poorly understood – concept of Quality of Life, which I will discuss, and for which I will present an account sufficient for the hence, early DBS surgery could facilitate relearning processes (Holloway et al., 2006).” Woopen et al, 2013. Pp. 83

Ibid.


Others appear to have arrived at the same dead end, searching for reports of DBS for psychiatric disorder in younger children: “To my knowledge, no case reports on DBS for psychiatric disorders in very young children exist.” F. Focquaert, 2013 ; “So far, psychiatric diseases in children have not been treated by DBS as the long-term outcome on mood is not yet known.” C. Woopen et al, 2013

purposes of this paper in subsection 3.2. In subsection 3.3. I will discuss two other concepts that are key for reaching clarity in the issues at stake, namely the concept of *Potentiality* and the concept of *the Interest of the Child*.

### 3.1. Risk & Benefit

When trying to identify the ethical concerns involved in paediatric DBS, the first things one ought to ask are: what are the risks involved? And what is to gain? Let us start with the latter question. As shown in section 2 of this paper, DBS is an effective method for treating conditions such as dystonia and tremor in paediatric populations. We also saw that it is more beneficial to the patient the earlier DBS treatment is employed as the improvement rate is higher in younger populations, and in early stages of disease. In conditions such as primary dystonia, there are also great benefits to be made through early intervention in avoiding orthopaedic deformations that could otherwise cause the patient great pain and suffering.\(^{34}\) As greater knowledge about brain plasticity in children is gained, chances are that (at least) the conditions treated with DBS in adult populations today will be offered to paediatric populations as well. This means that psychiatric conditions such as Tourette’s, OCDs and depression will be possible targets for DBS as a last resort treatment also for children. Assuming the treatment is successful, there are many benefits to be made from early implementation in psychiatric conditions. The social handicap that comes with severe Tourette’s syndrome or OCDs threatens the child’s ability to flourish, and may cause the child to be socially isolated. In severe cases of depression, anorexia, obesity or drug addiction, early implementation can very well be vital to save the child’s life.

As is the case with all invasive therapies, there are risks with DBS. Some potential harms that may follow DBS treatment are:

Intracerebral hemorrhages, dysarthria, worsening of apathy, depression, cognitive impairments (e.g., in verbal fluency, color naming, selective attention, and verbal memory), walking disturbances, sudden symptom reoccurrence and aggravation in case of battery depletion (occurring as a function of programmed stimulation parameters, usually after 5–13 months in the case of higher stimulation current amplitudes such as those

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\(^{34}\) C. Woopen et al, 2013
required for OCD) or of stimulation interruption, risking exacerbation of depressive symptomatology. Adverse short- and long-term effects on a psychosocial level might comprise psychosocial misadjustment, suicidal tendency, severe disappointment and renewed desperation in the case of non-responsiveness to DBS.35

Although some of these complications are unique, others are more common.36 The most common and serious type of complication is postoperative infection, with incidence rates of 5% – 33%, with higher rates being reported among paediatric populations.37 However, adverse effects following DBS treatment tend to be transient,38 and although these are all serious risks, they have to be considered in comparison with the alternatives. The first alternative is of course non-treatment. For some individuals with certain psychiatric conditions such as OCDs, Tourette’s and other tic disorders, this could sometimes be the better choice. These are among the more common neurological disorders in young paediatric populations, and often the symptoms are greatly reduced or even spontaneously remit over time. However, it is extremely hard to predict which patients will enjoy such a spontaneous recovery, and for which patients the condition will worsen. The number of patients that spontaneously recover is also substantially smaller than the number of patients that do not.39

If the choice is to try to treat the patient, there are two alternatives to DBS: other surgical treatments (i.e. Spinal Cord Stimulation (SCS)), and pharmacological psychiatric treatments. SCS is today only an alternative to DBS in cases of chronic pain40 and spastic movement disorders,41 and even in those areas the methods efficiency has been questioned.42 Far more common

35 M. Synofzik et al, 2008 p 5
36 The risk for “severe disappointment and renewed desperation” is potentially more imminent after DBS treatment compared to alternative treatments, as DBS is often regarded as a last resort treatment after all other alternatives failed. The risk is thus presumably just as imminent in any other treatment considered a ‘last resort treatment’. Nonetheless, it is de facto a potential harm in DBS treatments.
37 W. Marks et al, 2009
38 C. Halpern et al, 2007
39 Still, this uncertainty, in combination with the invasive character of DBS, has caused some to advise against using DBS for tics disorders in paediatric populations. N. Lipsman et al, 2010
40 M. Stojanovic, S. Abdi, 2002
41 M. Visocchi et al, 1994
42 R. Coffey, 2009
as an alternative to DBS are pharmacological treatments. The vast difference in kinds and amounts of medication between different conditions (also keep in mind the degree of disease) makes it difficult to provide a general analysis regarding potential harms and benefits of DBS contra pharmacological treatments – at least within the frame of this paper. A few aspects ought still to be highlighted on this topic. First, let us once again remind ourselves that DBS is still (and will plausibly continue be in the foreseeable future) a last resort treatment that is only used when other options are either not available, or have already failed. In this sense, pharmacological treatments are not always a real alternative anymore. Second, although many of us feel that it is less intrusive to take a certain medication than to connect an electrical device to the brain, there are some not negligible benefits to using DBS instead of medication. Regarding OCDs and major depressions (MD):

Compared to psychotropic drugs, it reversibly modulates only specific dysfunctional brain networks known to mediate mood and reward signals, but not widespread neurochemical brain circuits, many of which are unrelated to the pathophysiology of OCD or MD. This superior effectiveness is reflected by the fact that DBS was the only treatment in the psychiatric patients studied so far that was able to reduce symptom levels of MD and OCD, respectively, after many years of chronic disease and after many different unsuccessful treatment attempts using psychotherapy and psychopharmacology.43

This example is reasonably applicable to pharmacological treatments of other conditions as well. With medication disrupting the chemical balance in the patient’s body and/or brain, severe side effects are not only common, but also sometimes unpredictable due to the non-personalized medication of patients in today’s health care. This does not seem to be a problem for DBS patients. Third, if medication is taken under a long period of time or in large dosages, it is not always the case that the patient goes back to the same state she were prior to her starting to take the medication. On the contrary, a not uncommon drawback of psychiatric medication is that the patient develops an increased need to take the medication due to the new chemical balance.

43 M. Synofzik et al, 2008
That being said, in each case the parties involved in the decision making process ought to assess all options, and individual evaluations ought to be made for each patient. This makes the modelling of the decision making process extremely important, and we shall have a closer look at that in section 4.

3.2. Quality of Life

The benefits and risks of harm presented above are mostly effects that can be measured and studied. But there are also harms and benefits that are not best understood as medical effects, but as perceived burdens or reliefs: changes in personality, perceived changes in identity (or perceived changes in authenticity in relation to ones “real” self), changes in social behaviour or status, and in close relations – these are all important issues, and arguably more important than the strictly medical issues:

To provide an actual benefit to the individual patients [...] DBS must not only be effective, i.e., improve scores in OCD or MD rating scales, but also demonstrate that these abstract improvements indeed are associated with an actual improvement of the individual patient’s abilities to achieve personally valuable goals, i.e., goals that are valuable in light of his or her individual psychosocial situation and on the basis of his or her particular, individual evaluative concept of a good life.44

Despite this, non-medical effects are seldom accounted for in related publications.45 It seems these kinds of benefits and harms fall under what is often referred to as Quality of Life – a term central for an analysis of the value of performing a medical procedure, but one often vaguely defined. The first documented use of the term in a medical journal is by J.R. Elkinton in 1966, as he asks: “What is the harmony within a man, and between a man and his world – the quality of life – to which the patient, the physician, and society aspires?”46 Applauding the comprehensiveness of this formulation, Heinz

45 “For example, out of 20 studies and case reports regarding the use of DBS in cases of Tourette’s syndrome over the last few years we found that 11 contain no information about cognitive effects, [and] 9 contain no information about mood, social problems, and impact on quality of life” C. Woopen et al, 2012 p 1
46 J.R. Elkinton, 1966
Katchnig (30 years later) interpreted it to include three separate components, and made a suggestion on how to assess the concept in order for it to be useful in psychiatric practice: subjective wellbeing/satisfaction; functioning in social roles, and; external living situations (material and social). It seems that, as time moved on, the concept kept getting more and more refined. In 2002, a meta-analysis resulted in an identification and description of eight “core domains” of the concept of quality of life:

<table>
<thead>
<tr>
<th>Core QOL domain</th>
<th>Indicators and descriptors</th>
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<tbody>
<tr>
<td>Emotional wellbeing</td>
<td>Contentment (satisfaction, moods, enjoyment)</td>
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<tr>
<td></td>
<td>Self-concept (identity, self-worth, self-esteem)</td>
</tr>
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<td></td>
<td>Lack of stress (predictability, control)</td>
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<tr>
<td>Interpersonal relations</td>
<td>Interactions (social networks, social contacts)</td>
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<tr>
<td></td>
<td>Relationships (family, friends, peers)</td>
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<tr>
<td></td>
<td>Supports (emotional, physical, financial, feedback)</td>
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<tr>
<td>Material wellbeing</td>
<td>Financial status (income, benefits)</td>
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<tr>
<td></td>
<td>Employment (work status, work environment)</td>
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<td></td>
<td>Housing (type of residence, ownership)</td>
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<td>Personal development</td>
<td>Education (achievements, status)</td>
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<td></td>
<td>Personal competence (cognitive, social, practical)</td>
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<td></td>
<td>Performance (success, achievement, productivity)</td>
</tr>
<tr>
<td>Physical wellbeing</td>
<td>Health (functioning, symptoms, fitness, nutrition)</td>
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<td></td>
<td>Activities of daily living (self-care skills, mobility)</td>
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<td></td>
<td>Leisure (recreation, hobbies)</td>
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<tr>
<td>Self-determination</td>
<td>Autonomy/personal control (independence)</td>
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<td></td>
<td>Goals and personal values (desires, expectations)</td>
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<td></td>
<td>Choices (opportunities, options, preferences)</td>
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<td>Social inclusion</td>
<td>Community integration and participation</td>
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<tr>
<td></td>
<td>Community roles (contributor, volunteer)</td>
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<tr>
<td></td>
<td>Social supports (support network, services)</td>
</tr>
<tr>
<td>Rights</td>
<td>Human (respect, dignity, equality)</td>
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</table>

47 H. Katchnig, 1997 p 8
Although this list of domains is detailed and comprehensive in comparison to its predecessors, it ought also to be apparent that the domains of the list still contain a vast number of vaguely defined aspects and relations. This also leads to the list becoming almost impossible for concerned parties to assess and use in the decision making process. Let us take the domain of Emotional wellbeing as an example. The first descriptor of this domain is Contentment (satisfaction, moods, enjoyment). This could be understood in terms of an overall-type of question, where an assessment prior to surgery has to take into account the general sum of happiness, satisfaction and enjoyment of the patient. It also needs to take into account the expected increase or decrease of these variables post surgery, preferably in short-term as well as long-term prognoses. The final step is presumably to compare the present state to the expected state, and weigh the (assumed) benefit against the risks involved. Now, this is where it gets really tricky. Not only is it difficult for most people to “score” their feelings of overall happiness and satisfaction, and even more difficult to predict such a score. The score is also extremely dependent on the score of all other domains: the importance of material wellbeing, social inclusion and personal development for human wellbeing can hardly be understated. The second descriptor of Emotional wellbeing is Self-concept (identity, self-worth, self-esteem). Not only does it contain the patient’s feeling of being authentically and truly herself (a major issue for DBS patients) but it also contains issues regarding self-worth and self-esteem – again, issues highly dependent on other domains! We have yet to make it pass the first domain, and already major philosophical as well as practical questions arise.

So, although the list of domains is admirably comprehensive and detailed for its context, it is (1) still not detailed enough for a thorough ethical analysis, but also (2) too comprehensive and detailed to be of practical use in decision making processes. The second problem (2) is presumably even larger.

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48 R. Schalock & M. Verdugo, 2002
49 M. Schüpbach et al, 2006
in decision making processes concerning paediatric populations.\textsuperscript{50} Let us therefore briefly return to Katchnig. In concluding his paper on the usefulness of the concept of \textit{Quality of Life} in psychiatry, he writes:

In psychiatry, the art and science of quality of life assessment consists of capturing a patient’s quality of life midway between the two extremes of writing a novel on the one hand and summarising (?! quality of life into a single index on the other. It must also take a position between objective assessment and the indispensable subjective view of the patient. It has to be stressed that, despite the caveat described in this article, the subjective view of the patient should become a prominent voice in discussing the aims of psychiatric interventions, both on the individual and on the service/political level.\textsuperscript{51}

For the purposes of this paper, applicability of the concept of \textit{Quality of Life} is important, especially as it is of vital relevance in the decision making process (an issue we shall assess in Section 4). However, the project of providing an in depth analysis that results in a practical version of the concept is too large. Before concluding this subsection, I shall therefore only sketch a brief suggestion on how the concept ought to be understood and used in the context of neurosurgical interventions such as DBS.

First, on a purely conceptual and theoretical level, further research ought to be done in giving the concept of \textit{Quality of Life} a set of reasonable limits. In the context of medical prognosis, I suggest that it is to be separated as clearly as possible from external views on what quality of life amounts to (e.g. virtue ethics, and questions regarding ‘the good life’). This is to keep the concept limited so as to contain valuable domains \textit{as perceived by the patient}. This means focusing strictly on, for example, the patient’s own view on her social inclusion or self-determination, rather than other parties’ view in the patient’s inclusion. Although the latter aspect is important, it is for clarity’s sake better considered under other terms regarding risk-benefit assessment. Once this distinction is achieved, there are enormous amounts of literature in

\textsuperscript{50} Assuming children have a harder time grasping the abstract concepts at hand – an issue we shall discuss in Section 4.

\textsuperscript{51} H. Katchnig, 1997 p 9
ethics, philosophy and psychology concerned with the issues lifted in the domain list, as well as with related issues.

Second, on a practical level, a pedagogical and carefully crafted manual for how to assess issues concerning the concept of Quality of Life in decision making processes ought to be produced. Although it is easy to focus on the strictly medical issues (such as motor function, or social function as viewed externally) the wellbeing of the patient does not flow directly from those issues. It flows from the patient’s own experience and perception. Unable to provide such a manual in this paper, I merely repeat the words of Katchnig, that “the art and science of quality of life assessment consists of capturing a patient’s quality of life midway between the two extremes of writing a novel on the one hand and summarising quality of life into a single index on the other”.\footnote{H. Katchnig, 1997 p 9} Although I find his solution (the three components) somewhat too minimalistic for cases of paediatric DBS, it is a move in the right direction. If the parties involved require more information on the concept, such information needs to be available.\footnote{Perhaps starting with a "domain list"-type of explication, but not ending there.}

When using the term Quality of Life in the remainder of this paper, I will thus primarily refer to the practical interpretation as proposed by Katchnig. However, the reader is advised to keep in mind that the three components of this interpretation – wellbeing/satisfaction; functioning in social roles, and; external living situations – are to be understood, on my account, (1) purely as perceived by the patient, and (2) as containing the domains noted in the meta-analysis.

3.3. An Open Future

A less common, but nonetheless important value at stake, is the future autonomy of the patient. This is what Joel Feinberg calls “the child’s right to an open future”. The term stems from Feinberg’s paper with the same name, concerning the child’s “anticipatory autonomy rights”.\footnote{J. Feinberg, 2007} This also seems to be what Ross is after when arguing that “respect for children entails some respect for their current autonomy but also respect for the person they are
becoming.” Although Ross argues that this future autonomy of the child weighs in favour of a strongly paternalistic policy toward adolescents, Feinberg is more vague in his final judgement. Although he clearly thinks that the child’s right to an open future is important, he seems less certain regarding whom it applies to. The rights, classified as a child-rights, or “C-rights” (we are here particularly interested in the subclass of C-rights that he calls “rights-in-trust”) stands in comparison to adult-rights, or “A-rights”:

Among the rights thought to belong only to adults (“A-rights”) are the legal rights to vote, to imbibe, to stay out all night, and so on. [...] The rights which I shall call “C-rights”, while not strictly peculiar to children, are generally characteristic of them, and possessed by adults only in unusual or abnormal circumstances. [The] class of C-rights, those I shall call “rights-in-trust”, look like adult autonomy of class A, except that the child cannot very well exercise his free choice until later when he is more fully formed and capable.

In short, the idea is that the patient – being a child – has a right to have her future options kept open in the sense that she in the future will be as autonomous as possible. The concept of future autonomy is special in that it seems to transcend the risk-benefit/Quality of life distinction: to respect the future autonomy of the child is to try to see to it that she in the future is as autonomous as possible – both in a medical sense and in how she perceives her situation. I write “transcend”, as it appears that the concept will not let itself be reduced into the other two categories, but it supervenes on them. A child that runs the risk of never being able to walk by herself arguably has her future autonomy threatened – even if she in the future do not see it as a major issue (so that it is not a major threat to her Quality of Life). Also, even if the infrastructure of her society was to be constructed so that her not being able to walk is not a big physical obstacle (because of elevators, ramps etc.), it is still a threat to her autonomy if she perceives it as hindering her self-determination, physical wellbeing or social inclusion. In short, both the risk-benefit aspect and the Quality of Life plays important grounding roles in the child’s having an open future, but they do not constitute the concept as a whole. Feinberg

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55 L. F. Ross, 2004 p. 350
56 J. Feinberg, 2007 pp. 112 - 113
puts it well when he calls it “rights-in-trust”\textsuperscript{57}: it is a set of \textit{rights} that have been entrusted to the parents on behalf of the child. In virtue of being rights, they seem to transcend the distinction between the strictly medical condition, and the condition as perceived by the patient.

In this section I have identified what is at stake in paediatric DBS. I have argued that what we ought to take into account when making decisions about whether a patient ought to go through with the procedure or not is (1) the risks and benefits of the procedure, in a medical sense; (2) the quality of life as perceived by the patient; (3) the open future of the child, understood as the future autonomy of the patient. We shall return to discuss the implications of this for the actual decision making process, in Section 4.

4. Making Decisions: Autonomy, Decisiveness, and Consent

With a somewhat clearer view about what is at stake in paediatric DBS, it is now time to move on to discuss the decision making process. This section is divided into three subsections. In 4.1. I discuss issues concerning the concept of patient autonomy, including the autonomy of persons in general, and that of children and patients in particular. I will here suggest an account on how to understand the autonomy of children in relation to paediatric DBS. In subsection 4.2. I explicate and discuss how the proposed account of the autonomy of children affects the decision making process in terms of decisive authority and policy approach. I 4.3. I turn focus to the value of informed consent, and make a suggestion on how to construct the decision making process of paediatric DBS in order to make it ethically sound. I conclude that since the autonomy of the patient is not relevantly decided by age, but by the level of cognitive ability, most children that are within the normal span of potential DBS patients ought to be the ones to decide whether or not they ought to undergo DBS treatment. Finally, in 4.4, I explicate what it means to act in the best interest of the child, in the cases where the patient is not autonomous.

\textbf{4.1. The Autonomy of the Patient}

\textsuperscript{57} Ibid. p. 112
Along with beneficence and non-maleficence, the principle of autonomy of the patient is one of the most central concepts in health care. As a guideline for physicians, it is today almost universally accepted.\textsuperscript{58} A popular conception of the principle is that “to respect autonomous agents is to acknowledge their right to hold views, to make choices, and to take actions based on their values and beliefs.”\textsuperscript{59} This could mean several things, and in this subsection we shall have a closer look at the relevant aspects of the concept of patient autonomy, and analyse it in relation to paediatric DBS.

4.1.1. Autonomy as Capacity and Right

Before any other aspects of personal autonomy become relevant, it is commonly thought that the patient ought to possess a number of cognitive abilities in order to be seen as an agent capable of making decisions regarding her own health and wellbeing. Although there are many different accounts on how to define this capacity, they often share a number of attributes. Surprisingly Beauchamp & Childress, in one of the most influential books on biomedical ethics to date, avoid any extensive discussion on what makes a patient autonomous in terms of capacity, and simply state:

> Some theories of autonomy featuring the abilities, skills, or traits of the autonomous person [...] include capacities of self-governance such as understanding, reasoning, deliberating, managing, and independent choosing.\textsuperscript{60}

As the focus of this paper is paediatric DBS, the issue of autonomy as capacity is too important for us to settle with this weak account. A slightly more explicit account is presented by Joel Feinberg, when defining the capacity of autonomy (i.e. being a competent person) as a person’s mental ability to make rational choices.\textsuperscript{61} Feinberg distinguishes the competent person from the incompetent in the following way:

> A genuinely incompetent being, below the threshold, is incapable of

\textsuperscript{58} T. Beauchamp & J. Childress, 2013
\textsuperscript{59} Ibid. p 106
\textsuperscript{60} Ibid. p 102
\textsuperscript{61} J. Feinberg, 1989
making even foolish, unwise, reckless, or perverse choices. Jellyfish, magnolia trees, rocks, newborn infants, lunatics, and irrevocably comatose former “persons,” if granted the right to make their own decisions, would be incapable of making even “stupid” choices. Being stupid, no less than being wise, is the sole prerogative of the threshold-competent.  

Feinberg here talks of a “threshold”, referring to the border between persons who ought to be viewed as capacity autonomous and those who ought not to be viewed as such. However, once above this minimum threshold, the person’s autonomy is to be viewed as a matter of degree. Finally, Feinberg states that any person that is capacity autonomous also possesses autonomy as a right. This basically means that any capacity autonomous person has a right to have one’s decisions respected, and “the sovereign authority to govern oneself”.

### 4.1.2. Autonomy as Condition

Even if a patient satisfies the requirements of autonomy in terms of capacity, she may still be considered non-autonomous in another sense. Beauchamp and Childress note:

Even autonomous persons who have self-governing capacities and are, on the whole, good managers of their health sometimes fail to govern themselves in particular choices because of temporary constraints caused by illness, depression, ignorance, coercion, or other conditions that limit their judgement or their options. An autonomous person who signs a consent form for a procedure without reading or understanding the form has the capacity to act autonomously, but fails to act so in this circumstance.

This concerns, I take it, the aspect of personal autonomy that Feinberg calls “condition autonomy”. The concept is constituted by twelve virtues: (1) Self-possession; (2) Distinct self-identity (Individuality); (3) Authenticity (Self-selection); (4) Self-creation (Self-determination); (5) Self-legislation; (6) Moral authenticity; (7) Moral independence; (8) Integrity (Self-fidelity); (9)

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62 Ibid. p 30  
63 Ibid.  
64 Ibid. pp 47 - 51  
65 T. Beauchamp & J. Childress, 2013, p 102
Self-control (Self-discipline); (10) Self-reliance; (11) Initiative (Self-generation); and (12) Responsibility for self. Feinberg recognizes that although it is practically impossible to possess all of these virtues to the fullest, they are all important when analysing to what degree a person is condition autonomous.  

Asking what constitutes an autonomous action, Beauchamp and Childress provide a more compact alternative consisting in three conditions. The conditions are formulated to be coherent with the premise that the everyday choices of generally competent persons are autonomous. (1) Intentionality. “For an act to be intentional, as opposed to accidental, it must correspond to the actor’s conception of the act in question, although a planned outcome might not materialize as expected”; (2) Understanding. “Conditions that limit understanding include illness, irrationality, and immaturity. Deficiencies in the communication process also can hamper understanding. In our account, an autonomous action needs only a substantial degree of understanding freedom from constraint, not a full understanding or a complete absence of influence”; (3) Noncontrol. The patient must be “free of controls exerted either by external sources or by internal states that rob the person of self-directedness. [W]e concentrate on external controlling influences – usually influences of one person on another – but no less important to autonomy are internal influences on the person, such as those caused by mental illness. All of these conditions can limit voluntariness.”

Like Feinberg, Beauchamp and Childress recognize a difficulty in setting thresholds in regard to this type of autonomy. Although (1) Intentionality is not taken to be a matter of degree (“Acts are either intentional or nonintentional”), the conditions (2 - 3) are both virtues that the patient cannot be expected to live up to, to the fullest. Still, it is required by medical practise to determine whether the patient is autonomous or not. Beauchamp and Childress leave that issue for others to handle in particular cases:

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66 J. Feinberg, 1989, p 28 - 44
67 T. Beauchamp & J. Childress, 2013, p 104
68 Ibid. p 104
69 Ibid. p 104 - 105
70 Ibid. p 105
The lines between adequate and inadequate degrees of understanding and degrees of control must be determined in light of specific objectives of decision making such as deciding about surgery [...] The line between what is substantial and what is insubstantial may appear arbitrary. However, thresholds marking substantially autonomous decisions can be carefully fixed in the light of specific objectives such as meaningful decision making. [...] The appropriate criteria for substantial autonomy are best addressed in a particular context.71

The particular context, in our case, is paediatric DBS. We have now seen two different accounts of autonomy from two different sources: Feinberg presents a sharp philosophical analysis of the concepts of condition autonomy and capacity autonomy, and Beauchamp and Childress present a more minimalistic but also more practical interpretation of these aspects of autonomy. However, both accounts still seem to overlap to some degree. Let us therefore see what these accounts generate in terms of ascribing autonomy to paediatric DBS populations. For the remainder of this paper I shall primarily use the term “autonomy” as Beauchamp and Childress use it, as it is more practical than Feinberg’s account and sufficient for our purposes. If further analysis of the concept is needed, however, I recommend Feinberg’s account as a point of reference, as it is plausibly the most exact and comprehensive account to date.

4.1.3. Autonomy and Decisiveness

Both in terms of capacity autonomy and in terms of condition autonomy, the statuses of potential paediatric DBS patients vary greatly. This is perhaps sometimes the case due to differences in maturity, but probably more often due to the variety of medical conditions:

Children can understand and assess medical issues according to their age. They can increasingly decide for themselves which procedure they want and which one they don’t want. Many of the children with dyskinetic or dystonic movement disorders are only mildly cognitively impaired or even have a normal cognitive function. These patients can be fully informed about the DBS procedure and, therefore, they are able to give their assent

71 Ibid. p 105
to or their dissent from DBS. Unfortunately, some of them suffer of severe dysarthria or anarthria due to oropharyngeal dystonia with severely impaired communication abilities. These patients are hardly able to ask relevant questions about the DBS procedure; therefore communication aids such as an eye-tracking-computer are essential for communication and have to be used for full participation of the child in the decision process. Children with distinct cerebral injury can be severely mentally impaired and are therefore not able to give assent to DBS.\textsuperscript{72}

With this great variety in mental capacity and condition autonomy in mind, I shall henceforth in this paper organise the potential paediatric DBS patients into three groups: Paediatric Deep Brain Stimulation (PDBS) 1-3.

- **PDBS1**: The patients in this group are capacity autonomous and condition autonomous to an adequate degree.
- **PDBS2**: The patients in this are capacity autonomous, but not condition autonomous to an adequate degree.
- **PDBS3**: The patients in this group are neither capacity autonomous, nor condition autonomous to an adequate degree.

I shall later in this paper argue that each of these groups ought to be treated in separate ways during the decision making process. Before getting to that, however, we ought to acknowledge a few distinctions regarding decisiveness in decision making. *Decisiveness* is here to be understood as a power of authority in decision making. If the will of a patient is considered *structurally decisive*, her will ought to be respected regardless of any other reasons there may be for or against going through with the treatment. A patient’s will carries *substantial relevance* if her will is a factor among others to be weighed in, in the total sum of factors. Finally, a patient’s will is *substantially decisive* if it is the factor that decides the outcome of the decision making process – not because of respect for autonomy (as is the case of structural decisiveness) but because it is rational to do so for other reasons. These distinctions are persuasively argued for by Daniel Groll, when comparing the hypothetical cases of Bob (an autonomous patient whose will is structurally decisive) and

\textsuperscript{72} Woopen et al, 2013 p 84
Carl (a patient who lacks capacity autonomy, and whose surrogate makes decisions for him). In these cases, both patients have expressed a will not to go through with a certain treatment, even though going through with the treatment would be best for them.73

[T]he force of the reason not to do the surgery that is grounded in Bob’s demand is insensitive to considerations of Bob’s good. This means that the doctor cannot discount Bob’s demand by pointing out that following it is not good for Bob. Relatedly, the normative force of Bob’s demand is not properly assessed by determining what good (for Bob) comes from following it. The point of an authoritative demand in this context is to render such appeals to what is good for Bob, at least on the part of the doctor, irrelevant.

[...] The situation with Carl is very different. Since Carl is incompetent, he cannot make authoritative demands. And this means that Carl is not the de jure ultimate decision maker with regard to the decision to have surgery—someone else is the proper decision maker. [...] Does this mean that Carl’s will—his expressed wish not to have surgery—can play no role in the surrogate’s deliberation? Not at all. It is just that Carl’s will to not have surgery is one factor among others that goes into an all-things-considered judgment about what is good for Carl. In other words, the relevant question is whether it is good (for Carl) to follow his will in this situation. It might turn out that what is best for Carl is letting him have his way because it is his way.74

The case of Bob is rather straightforward: He is a competent75 and autonomous patient, that ought to have his will respected regardless of whether his decision is to be considered good for him or not. This is, I take it, an example of how the Feinbergian right autonomy works in practice. Since

73 D Groll, 2012
74 D. Groll, 2012 pp 701 - 703
75 It is not entirely clear what Groll means by "competent". It could refer to the combination of "capacity autonomy" and "condition autonomy" (here simply “autonomy”) but as I have interpreted it, it refers to capacity autonomy only. I have drawn this conclusion on a semantic basis: Feinberg mentions that “right autonomy” can also be called “de jure autonomy”, and that the only requirement to possess such autonomy is that the person be capacity autonomous. Groll writes that Carl is “not the de jure ultimate decision maker”, and that the reason for this is that Carl is incompetent. J. Feinberg, 1989 pp 47 – 66 ; D. Groll, 2012 p 702
the patient is autonomous, he has a right to have his will respected – his will is structurally decisive. This is not the case regarding Carl, however. Since he is incompetent, he does not have the right to make the final decision. However, Groll argues, perhaps Carl’s will can be substantially relevant – maybe even substantially decisive. Let us sum up what this means.

- Structurally Decisive: The patient is autonomous, and ought therefore to have her will respected.
- Substantially Relevant: The patient is not autonomous, and her will is therefore not structurally decisive. However, it may still be rational for the surrogate to take the will of the patient into consideration in the decision making process.
- Substantially Decisive: The patient is not autonomous, and her will is therefore not structurally decisive. However, it may still be rational for the surrogate to take the will of the patient into consideration, and even to let the will of the patient be the decisive factor in the decision making process.76

This being settled, let us now put together the pieces that we have gathered so far in regard to autonomy and decision making in paediatric DBS. According to Woopen et al, many patients can be “fully informed about the DBS procedure and, therefore, they are able to give their assent to or their dissent from DBS.”77 This indicates that many paediatric DBS patients can make decisions concerning their own health intentionally and with a full understanding of the procedure and its effects. This satisfies conditions (1-2) in Beauchamp and Childress’s autonomy account. It also indicates that the patients are capacity autonomous and largely condition autonomous. The only real worry here seems to be condition (3) in Beauchamp and Childress’s account, noncontrol. It is possible, perhaps even plausible, that the influence of the child’s parents or caretakers renders the child “controlled”. We shall have a closer look at this problem in the next subsection (4.2), regarding the responsibilities of the parents. Given that this worry is sorted out, however,

76 D. Groll, 2012
77 C. Woopen et al, 2013 p 84
this group of children ought to be considered autonomous to an adequate degree, and are therefore included in the group I have above labelled PDBS1. At this point it is hard to see any good reason why the will of a member of this group ought not to be considered structurally decisive, since she is competent and autonomous. This means that any appeals to the patient’s future autonomy, or right to an open future, are trumped.

All children considered for DBS, however, are not this autonomous. Woopen et al writes that some patients have severely impaired communication abilities and that these patients “are hardly able to ask relevant questions about the DBS procedure; therefore communication aids such as an eye-tracking-computer are essential for communication and have to be used for full participation of the child in the decision process.” This group of patients falls into the category I have above labelled PDBS2. They are not condition autonomous to an adequate degree, as they suffer from impairments that limit their ability to participate in the decision making process. However, they seem to be capacity autonomous in that they have the mental ability to understand many aspects of the procedure and its effects if informed in a proper way, and they can clearly intend to have the treatment, or to not have it. I propose that their will be considered substantially relevant/decisive. The patient is not fully autonomous, and is highly dependent on her parents’ understanding and communicating information of the procedure as well as the will of the patient. Still, the patient’s capacity to understand the situation ought to make it rational for the parents to take the will of the patient into consideration to a high degree.

The third group of patients, PDBS3, lacks capacity to understand the procedure and its effects. The patients’ ability to participate in the decision making process is therefore extremely limited. Woopen et al write that “children with distinct cerebral injury can be severely mentally impaired and are therefore not able to give assent to DBS.” Other patients that probably ought to be included in this group are very young children. The will of these patients ought also to be considered substantially relevant, and perhaps substantially decisive. However, the decision making process concerning

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78 C. Woopen et al, 2013 p 84
79 C. Woopen et al, 2013 p 84
group PDBS3 ought still to differ from that of children of group PDBS2, as I shall argue below.

4.2. *The Structure of the Decision Making Process*

There are three major positions regarding the decision making process of paediatric health care: the *Protectionist* position, the *Liberalist* position, and the *Shared Decision Making* position.\(^{80}\) The perhaps most common position taken by ethicists and medical experts is the protectionist position.\(^{81}\) This position lays the decisive authority in the hands of the patient’s parents. Some of the core arguments are that: (1) Parents are responsible for bringing up their children, and that responsibility necessarily requires having rights for decision making; (2) Apart from the children, parents will be the ones most likely to have to live with the consequences of any decisions made; (3) Parents know the child best; and (4) Affection and close family ties make parents most likely to reach decisions based on the child’s best interest.\(^{82}\) One could also, like Ross, make an argument from future autonomy: it is not only the current autonomy of the child that is at stake, but also her future autonomy. Since the child herself is unable to grasp such a vague concept as “future autonomy”, but her parents are able to do so, they thereby gain authority over the decision making.\(^{83}\) Some proponents stresses that the optimal decision making process includes the views of the child, but that the parents still ought to have the final say.\(^{84}\)

On the other side of the spectrum, we have the liberalistic position. In the light of children often showing unexpected maturity in issues regarding their own health, one could argue that the child ought to have decisive power. I have not found any literature arguing argue structural decisiveness for all children. For various reasons it is also often made impossible by law. But there are certainly some that lean more toward a more liberalistic approach. Lynn Hagger argues:

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\(^{80}\) The labels are here used in the same way as in F. Focquaert, 2013. More information about the positions can be found there.

\(^{81}\) A. Buchanan, D. Brock, 1989 ; C. Cummings, M. Mercurio, 2010 ; R. Ladd, E. Forman, 2010 ; L. Ross, 1998

\(^{82}\) E. Forman, R. Ladd 1996

\(^{83}\) L. Ross, 2004

\(^{84}\) R. Ladd, E. Forman, 2010
An important aspect of the responsibilities of parents is to ensure their children achieve competent adulthood. Children need to gain experience of decision-making to practice their skills on the road to reaching ‘a capacity where they are able to take full responsibility as free, rational agents for their own system of ends’. Responsible parents should give weight to the child’s views given the empirical evidence that children are capable of making significant decisions at very young ages. The proposal here is that a rights-based approach where the focus is on the individual child, at least initially, can help to challenge the lack of attention paid to children generally and emphasize their need to be involved in decision-making.

From a liberalistic position, the argument is thus not that children ought to be made autonomous in the legal sense. Rather, the idea is that health care policy ought to stress the importance of children’s rights, and therefore act upon the will of the child as much as possible. Structural decisiveness could therefore be plausible in some cases, but less reasonable in other.

Finally, a middle path is possible. Weighing the pros and cons of protectionist and liberalistic positions in relation to paediatric DBS, Farah Focquaert instead argues for a shared decision making process, where “parents or parental guardians should give their consent and the child his/her assent before treatment can take place.” Moreover, if the patient is unable to fully understand the procedure and its consequences due to developmental immaturity the treatment ought to be postponed “unless we can accurately predict that the child would benefit from treatment and would be harmed if left untreated.”

Focquaert does not state what ought to be done in such cases, however. This is a rather restrictive account, where both the patient and her parents respectively have a sort of veto. If any party says ‘no’, the treatment will not take place unless it can be proven that the treatment will benefit the patient, and that it will not harm her.

Ending this subchapter, we shall now add these final pieces to finish

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85 L. Hagger, 2009, p 69
86 Note that Hagger does not argue for structural decisiveness, but rather an increased involvement of the child in the decision making process where the assent of the patient is valued – not that consent ought to be required.
87 F. Focquaert, 2013 p 454
88 Ibid. p 454
89 From her discussion concerning the protectionist approach, it seems that Focquaert incorporates the concept of Quality of Life into ‘benefit’ and ‘harm.’
the puzzle. The matches that I propose are the following:

<table>
<thead>
<tr>
<th>Group</th>
<th>Patient Authority</th>
<th>Policy Approach</th>
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<tbody>
<tr>
<td>PDBS1</td>
<td>Structurally Decisive</td>
<td>Liberalistic Approach</td>
</tr>
<tr>
<td>PDBS2</td>
<td>Substantially Relevant/Decisive</td>
<td>Shared Decision</td>
</tr>
<tr>
<td>PDBS3</td>
<td>Substantially Relevant/Decisive</td>
<td>Protectionist Approach</td>
</tr>
</tbody>
</table>

As patients falling under the PDBS1 classification possess autonomy to a degree sufficient for making decisions regarding health care, there are few (if any) good arguments why these patients ought not to enjoy a structurally decisive force of will. As long as they are capable of intending and understanding the treatment, its risks, benefits, and potential effects (and the corresponding issues regarding alternative treatments and non-treatment) the only aspects that restrict their ability to practice full autonomy are noncontrol and legal protection of parental rights. The issue of noncontrol can be partly handled through a well-structured decision making process where the patient has access to a psychologist trained in assessing coercion (or a medical expert with corresponding expertise). However, the parents carry a heavy responsibility in not trying to talk the patient into making decisions she does not wholeheartedly wish to make. Again, we shall have a closer look at this issue in the next subsection.

The issue of legal protection can at first glance be taken to be more problematic. As the patients of group PDBS1 are not legally autonomous, the parents have the right to make the final decision, which might lead one to think that the will of a paediatric patient cannot be structurally decisive in real life situations – the parents will always have the right to decline or accept the treatment in the end, regardless of what the will of the patient is. This is not necessarily the case, however. A policy can still be formulated where the autonomy of the paediatric patient is highly valued. If a situation emerges where DBS treatment is advised by medical expertise and the patient accepts, but the parents decline, there are further steps to be taken to protect the child. First, of course, one ought to try and explain the treatment, its risks, benefits, and potential effects again, and assess the worries of the parents through

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90 This solution is suggested by Focquaert. F. Focquaert, 2013
dialogue with medical and ethical expertise. If this does not result in consensus, legal measures can often be taken to ensure the wellbeing of the child.\textsuperscript{91} If the case for treatment is strong enough (as it should always be, regardless of there being consensus in the decision making process) a court ought to rule in favour of the child. If a situation emerges where the positions are the opposite (the child declines, the parents push for treatment) a case can also be made for protecting the child. In both of these cases, the child ought to be protected in accordance with the United Nations’ Convention on the Rights of the Child (CRC). Article 12 of the CRC states that “States Parties shall assure to the child who is capable of forming his or her own views the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child.”\textsuperscript{92} Article 23 states that “States Parties recognize that a mentally or physically disabled child should enjoy a full and decent life, in conditions which ensure dignity, promote self-reliance and facilitate the child’s active participation in the community.”\textsuperscript{93} All in all, I propose a liberalistic policy approach toward patients in group PDBS1 due to the importance of respecting patient autonomy in health care.

Patients falling under the PDBS2 classification do not possess autonomy to a degree sufficient for making decisions regarding health care. Although they essentially possess the capacity to understand the issues at stake, due to their medical conditions they are in a situation where they cannot process the relevant information without assistance. For this group of patients, I therefore propose a shared decision approach where the view of the parents ought to weigh heavier than in group PDBS1 cases. The patient is highly dependent on the parents’ communicating the relevant information – both regarding the treatment in the direction of the child, and regarding the will and view of the child in the direction of the medical team. That being the case, it can still be rational for the parents to let the will of the child be the decisive factor in the decision making process. Such an approach ought therefore to be promoted through policy. Due to the possibility of a deadlock situation (the shared decision approach requires all parties to accept

\begin{itemize}
\item \textsuperscript{91} At least in most countries.
\item \textsuperscript{92} Officer of the High Commissioner for Human Rights, 2014
\item \textsuperscript{93} Ibid.
\end{itemize}
treatment), the risk of coercion is high and policy ought to stress the importance of letting the true views of the child be laid bare.

Patients falling under the PDBS3 classification do not possess the capacity to understand the information relevant for the decision making process. Therefore, patients in this group are not autonomous. It can be rational for the parents to take the will of the child into consideration, and even to let it be decisive. Still, the interest of the child is the central issue of the decision making process in these cases, and ought to be the heaviest weighing aspect. 94 The parents’ unique position to understand and communicate with their child puts a great responsibility on them to make the final decision. I therefore propose a protectionist approach be taken toward patients in group PDBS3.

4.3. Informed Consent, and the Responsibilities of the Parents
As the degree of patient autonomy varies in the groups PDBS1-3, so do the responsibilities of the parents. In this subsection, we shall look at the implications of the different degrees of patient authority and policy approaches for the informed consent process, and what can be expected from the parents of patients in the groups PDBS1-3.

The doctrine of informed consent is an ethical and legal doctrine expressing the patient’s right to self-determination and the doctor’s duty to provide “information about proposed treatment so as to provide him or her with the opportunity of making an ‘informed’ or ‘rational’ choice as to whether to undergo the treatment.”95 For this to be the case, it ought primarily allow the patient to make an autonomous decision.

[T]here must be a disclosure of all the relevant information (including both benefits and risks); the patient must fully understand (comprehend) both the information which has been given and the implications of giving consent; the consent must be voluntarily given (i.e. the patient must be free of coercion or manipulation); and, lastly, the patient must be competent to consent (i.e. be both ‘rational’ and prudent).96

94 What the interest of the child amounts to is explicated in subsection 4.4. of this paper.
95 G. Robertson, 1981. p 102
96 M. J. Johnstone, 2009. p 149
These aspects (disclosure; understanding; voluntariness; and competence) are what is on the table when we below shall look for solutions regarding informed consent in groups PDBS1-3, and the responsibility of the parents of children in each group. Starting with PDBS1, I have argued that the rights of parents of children in this group ought not to have precedence when it comes to making the final decision regarding whether or not DBS treatment should be implemented. This, however, does not free the parents from responsibilities concerning informed consent. The parents are still – legally and ethically – responsible for the health and wellbeing of their child. Together with the medical experts, the parents are obligated to see to it so that all relevant information is disclosed and understood by the child. For the parents, this means familiarizing themselves with the treatment’s risks and benefits, contemplating the potential quality of life and future autonomy of the child (in relation to any alternative treatments and nontreatment) and communicating this to their child in an accessible manner. It also means actively engaging in the decision making process by asking questions and making sure that the child follows and understands what is being discussed.

As the child presumably looks to its parents for guidance, the issue of voluntariness\(^\text{97}\) is a more delicate one. When does an “advice” or a “point of view” turn into manipulation or coercion? As proposed earlier (following Focquaert), the patient ought to be presented with the opportunity to talk to a psychologist with knowledge in the mechanisms of coercion, or a medical expert with corresponding expertise, under the course of the decision making process. However, it is ultimately the responsibility of the parents to see to it that their opinions and advice are presented as such, and make clear for the child that they will care for and support her regardless of her final decision. In cases where parents fail to work in favour of patient voluntariness, it is the moral obligation of the health care professionals and the psychologist to see to it that the parents either change how they assess the issues at hand, or are excluded from the process (either by convincing them or, if necessary, by legal

\(^{97}\) This is the issue that Beauchamp and Childress referred to as "uncontrol". T. Beauchamp & J. Childress, 2013
It is therefore of great importance that all adult parties involved in the decision making process are aware of all these aspects.

Regarding group PDBS2, the parents have a greater role to play. Not only are they essential for the communication between the child and the health care professionals, but also they are partly responsible for making the final decision. This makes it extremely important that they are engaging in the decision making process, and that they can properly assess what is in the best interest of the child, including the risks and benefits, the quality of life and her future autonomy, with all that it amounts to. If consensus is not reached, they will also have to establish a dialogue with the child, thoroughly discussing the issues without manipulating her or talking her into making a decision she does not wholeheartedly wish to make. Once again, it is up to all adult parties to be observant at this stage. If possible, a psychologist ought to assess such issues privately with the patient. It is important that the parents together with the medical experts make sure that all relevant information is disclosed and accessible for the patient, as she has the capacity to understand the information if presented with it in an appropriate way.

Finally, parents of children in group PDBS3 ought to be encouraged to include their child as much as possible in the informed consent process, even though the child may not have the mental capacity to fully understand what issues are at stake. She may still understand some of it, and her will in regard to what she can understand ought still to be substantially relevant. However, as the patient herself in this case cannot meet any criteria but voluntariness, much of the informed consent process rests on the parents’ ability to gain and process relevant information, and make decisions based on what is in the best interest of the child.

4.4 Acting in the Interest of the Child

Any medical intervention, it is commonly thought, ought to strive to be beneficial to the patient. But when treating paediatric populations, the patients are not always autonomous to a degree sufficient to decide what is

98 Of course, parents have the right to ask questions and discuss issues related to the future care of the child, and what complications may follow the procedure. These issues can, however, be assessed at a point where the child is not present. This applies to parents of children in all groups.
best for themselves. In these cases, we resort to the concept of the Interest of the Child (IoC). This concept is important for the decision making process of paediatric DBS – especially regarding groups PDBS2-3 – and we ought therefore to make a few clarifications on what this term amounts to. Cummings and Mercurio notes:

It is expected that parents will decide for a child based on their assessment of the child’s best interest. Such judgments, however, are often difficult and subjective.

It is not uncommon that in articles on ethics in paediatric health care, the concept of IoC plays an important role. Still, there is seldom any further information about what IoC really amounts to. Some writers explicate a little on this and similar concepts. Beauchamp and Childress write, regarding what they call the Best Interests Standard:

Under the best interests standard, a surrogate decision maker must […] determine the highest probable net benefit among the available options, assigning different weights to interest the patient has in each option balanced against their inherent risks, burdens, or costs. The term best applies because of the surrogate's obligation to act beneficently by maximizing benefit through a comparative assessment that locates the highest probable net benefit. The best interests standard protects an incompetent person’s welfare interests by requiring surrogates to assess the risks and probable benefits of various treatments and alternatives to treatment.

It is not entirely clear in what ways the Best Interests Standard relates to the concept that in this paper is called Quality of Life, and to risk and benefit; what are the “interests” that the patient has, that have to be balanced against the “inherent risks, burdens, or costs”? In order to make this paper as clear as possible, I will below construct a rough account on how to understand the concept of IoC.

99 C.L Cummings & M.R. Mercurio, 2010 p. 254
100 T. Beauchamp & J. Childress, 2013 p. 228
As indicated in the introduction of this subsection, the IoC is an important concept to keep in mind when making medical decisions where the patient is a non-autonomous child – plausibly the single most important. Unfortunately, the IoC is a complex concept: it can trump the informed consent or dissent of the patient; it needs not only take into account the present medical and perceived condition of the patient, but also the medical and perceived condition of the patient’s future self; and it needs to take into account both the present and the future autonomy of the patient. If it comes to a situation where the parents of a patient have to make a decision about whether or not their child is going to go through a DBS treatment, it can therefore be a very difficult task for them to figure out what lies in the best interest of the child. What is at stake here?

First, most would agree that the health of the child is central, regardless of whether we talk about the child now or the future person that the child will develop into. This means that the parents ought to weigh in the risks and benefits of (1) DBS treatment, (2) any alternative treatments, and (3) non-treatment. This weighing need not always be as “difficult and subjective” as Cummings and Mercurio claim. With the proper help and advice from medical expertise, the parents can be guided quite well through the pros and cons. As DBS is mostly still considered a last resort treatment, the alternative treatments are also often few or non-existent. In short, it is reasonable to include the medical aspects of wellbeing and functioning in the practical assessment of the IoC.

Second, as stated in Section 3, in order for the treatment to actually be beneficial to the patient, it needs to improve “the individual patient’s abilities to achieve personally valuable goals.”\textsuperscript{101} This concerns what I in this paper have called the Quality of Life. This concept is more tricky for the parents to consider, for two reasons: (1) it can be difficult to know what the patient perceives as important values, and how she weighs them against each other – especially if there are problems in the communication between the child and the parents due to the illness or immaturity of the patient, which is not uncommon in groups PDBS 2-3. Also, (2) there is the problem of trying to predict the future quality of life of the patient. Even for a competent person it

\textsuperscript{101}M. Synofzik et al, 2008 p 5.
is hard to predict what one will value in 10 years time. In the cases where the IoC kicks in as an important factor, the patient is not competent to predict this herself, and can be difficult to communicate with. This hardly makes things easier. Nonetheless, the parents will have to try to assert these values as best they can.

Third, and last, there is the child’s right to an open future. This concept, also referred to as the “future autonomy” of the child was presented and explained in subsection 3.3. of this paper. The main content of this concept was that children have “rights-in-trust” – that is rights that children do not yet possess in the same sense as adults do, but that nonetheless need to be respected as the child will, or ought to be able to, exercise in the future.

Now, Feinberg seems to argue that many of the rights-in-trust are generally to be entrusted to the parents. However, he complicates the picture somewhat:

There is no sharp line between the two stages of human life; they are really only useful abstractions from a continuous process of development every phase of which differs only in degree from that preceding it. Many or most of a child’s C-rights-in-trust have already become A-rights by the time he is ten or twelve.102

Exactly which rights have transformed, and to what degree, is left unsaid. This makes it difficult to see what Feinberg would make of the structure of the decision making process that I have proposed. Precisely where Feinberg would have drawn the line is not of great importance to us, however. The important thing is the content of the concept of future autonomy, or an open future. This aspect of the IoC is special in that it transcends the risk-benefit/Quality of life distinction: to respect the future autonomy of the child is to try to see to it that she in the future is as autonomous as possible – both in a medical sense and in how she perceives her situation. Regarding the concept’s medical sense, the parents ought to find sufficient support among the health care professionals. Regarding the sense in which the patient will perceive her autonomy in the future, the parents will reasonably have the same problem as when trying to assess the future Quality of Life of the child: it

102 Ibid. p 121
is extremely difficult to predict such a subjective and distant issue. Nonetheless it is an important aspect of the IoC, and the parents will have to assess it the best they can.

To summarize, then, the concept of the Interest of the Child is made out of three constituents: (1) the chance of benefit, and risk of harm, that may come to the child if she goes through with the treatment; (2) the present and future Quality of Life of the child; and (3) the child’s right to an open future. All these constituents ought to be carefully weighed in the context of any alternative treatments that may be relevant, and the possibility of non-treatment.

5. Conclusion

In the context of paediatric DBS, several ways of constructing the decision making process have been discussed. While some writers propose a protectionist approach, where the parents have most of the decision making power, others have argued for a more liberalistic approach where the children gets to decide for themselves. Others have argued for a shared decision making process, where consent from both the child and the parents are required, and yet others state that we have to judge case by case. I have argued for a structure of the decision making process where patients are given more or less decisive power depending on their level of autonomy. But the structure I propose is also more precise and guiding than the not uncommon suggestion that we ought simply to judge case by case. I propose that, depending on the degree of autonomy the patient possesses, she ought to have decisive power and policy support accordingly, in the following way:

<table>
<thead>
<tr>
<th>Group</th>
<th>Patient Authority</th>
<th>Policy Approach</th>
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<tbody>
<tr>
<td>• PDBS1</td>
<td>Structurally Decisive</td>
<td>Liberalistic Approach</td>
</tr>
<tr>
<td>• PDBS2</td>
<td>Substantially Relevant/Decisive</td>
<td>Shared Decision</td>
</tr>
<tr>
<td>• PDBS3</td>
<td>Substantially Relevant/Decisive</td>
<td>Protectionist Approach</td>
</tr>
</tbody>
</table>

I believe that this solution can be justified by a reasonable account of patient autonomy, and a plausible estimation of the weight of that autonomy in relation to other values (parental rights, the interest of the child etc.). I have
argued that the parents of children that are sufficiently autonomous to make their own decision have an obligation to not control the child, but to help her to collect information about the treatment and to understand its implications. This is even more important in cases where the child is partially autonomous, but unable to communicate properly without help. I have also argued that, where the child is not sufficiently autonomous to make the final decision herself, the central issue ought to be whether the treatment is in the best interest of the child. This concept, which I have called IoC, amounts to the risks and benefits involved in the treatment (in a strictly medical sense), the quality of life of the patient (in subjective sense, from the perspective of the child), and the child's right to an open future.

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