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# The condition of informed consent regarding technical interventions in the brain

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Jan-Christoph Heilinger, Berlin-Brandenburgische  
Akademie der Wissenschaften, Berlin  
Markus Christen, Universitärer Forschungsschwerpunkt  
Ethik, Universität Zürich

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# Overview

- **The Problem:**
    - A case report
    - Informed consent
  - **Deep Brain Stimulation:**
    - Operation mode
    - Applications
  - **Autonomy & agency:**
    - Concepts
    - Propositions
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# The Problem – Case report (1)

The patient had to be at least 18 years, and no more than 60 years of age. He must be able to understand, comply with instructions and provide his own written informed consent. The patient and a close family member were repeatedly and fully informed on both procedures (capsulotomy and DBS). The standard risks for DBS, known from its use in Parkinson's disease (PD) were explained. Criteria excluded a current or past psychotic disorder, any clinically significant disorder or medical illness affecting brain function or structure (other than motor tics or Gilles de la Tourette syndrome) or current or unstably remitted substance abuse. If the patient did not improve after 1 year of DBS, the option of anterior capsulotomy would be reconsidered.

Gabriëls et al. Acta Psychiatr Scand 107  
(2003): 275-282

# The Problem – Case report (2)

*Case 3.* Case 3 is a single woman of 38 years with onset of symptoms at 16 years and a family history positive for OCD. She worked in administration until the age of 32 but lost her job because of the severity of her symptoms. Becoming completely non-functional she returned home to live with her parents. The main symptoms are intrusive sexual thoughts and impulses; excessive toilet, washing and counting rituals; compulsive buying and the urge to touch. She was preoccupied by the thought that objects and things might not be real, might not exist, and had a whole series of compulsions to ensure that they were really there. She fulfilled criteria for dependent personality disorder with a pattern of a constrictive, self-pitying, helpless and anxious patient, utterly dependent on significant others.

Gabriëls et al. Acta Psychiatr Scand 107  
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# The Problem – Case report (3)

Immediately after stimulation her attitude changed remarkably. From the first week, she was less anxious and felt more relaxed and easy-going. Her parents conclude: 'If she had made a pilgrimage, we would have thought a miracle had happened'. Some remaining compulsions hardly interfered with social activities and she was able to control and resist them a lot better. Relief of symptoms was markedly clear and reproducible by switching DBS on. With stimulation she was very active during the day. She reported feeling more cheerful and bustling, experiencing more excitement, talking louder and faster and laughing more. She sometimes seemed disinhibited, but did not engage in risky, reckless or impulsive behaviours.

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# Informed consent

## **Informed consent**

is the *process* by which a patient can participate in choices about his healthcare (surgical or medical procedure, inclusion in a clinical study). It originates from the legal and ethical rights the patient has to direct what happens to his body and from the ethical duty of the physician to involve the patient in decisions about his healthcare.

### ***The physician provides to the patient:***

- Information about the procedure and the decision at hand
- Explanation of alternatives
- Facts about risks, benefits, and uncertainties of all alternatives

→ *acceptance/rejection of the intervention by the patient*

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# Conditions of informed consent

- Patient is understanding
- Patient is competent to make decisions
- Patient makes his choice voluntary and autonomously
  - not forced

→ ***Risk of forced choice, subtle coercion by unfavorable circumstances***

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# Restrictions of an informed consent

In some (psychiatric) cases, the patient is:

- not able to understand his situation
- not able to understand the risks and benefits
- not able to decide rationally
- not able to communicate his decision

→ ***The capacity of decision-making is variable, as lucid states and disordered states alternate.***

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# Ways out

- Presumed consent has to be figured out with a surrogate decision maker (near relatives, care giver, medical attendant)
  - Legitimization of an intervention has to be postponed, until ability to decide is restored
- *Analogy to the debate about the use of psycho-pharmaceutics*
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# The Problem – Our question

**Our Focus:** One particular type of technological intervention:  
*Deep brain stimulation for psychiatric disorders.*

**Why DBS?**  
(compared to  
psycho-pharmaceuticals)

- Defined locus
- Defined stimulation
- Reversibility

**Our question:** *(How) can DBS be used to raise autonomy and agency in psychiatric patients, thus supporting the concept of informed consent?*

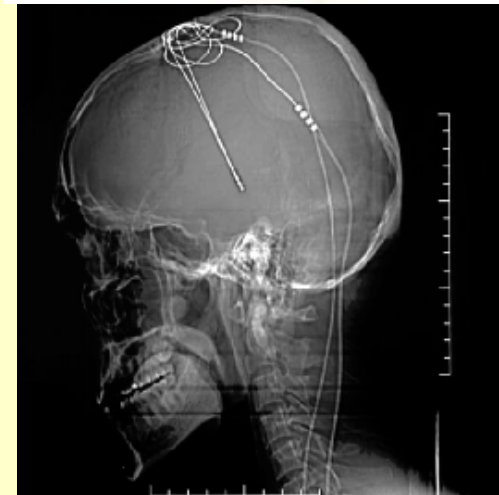
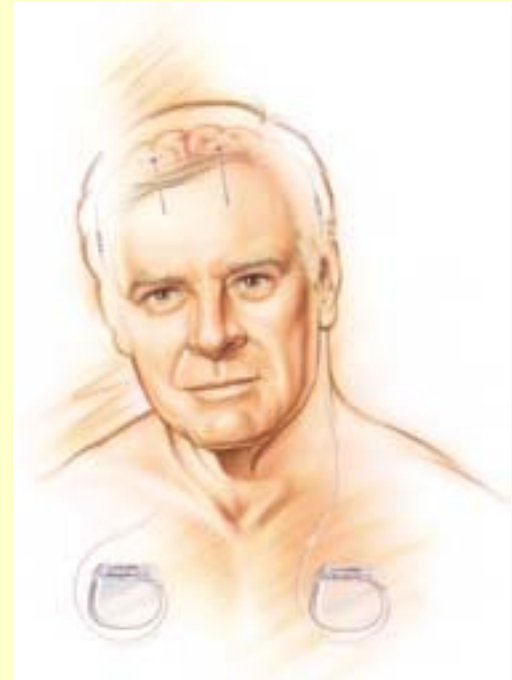
Thus expanding the idea: “DBS can be turned on and off,” DeLong points out. “It is relatively noninvasive, nondestructive and reversible.” Used correctly and with the proper informed consent from patients, he says, DBS has the potential “to help us dissect the neural pathways underlying depression, all the pathways and substrates, as it has with movement disorders.” (DANA, 2005)

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# DBS – Operation mode

## Key elements:

- Based on pacemaker-technology (Medtronic has basically a monopoly)
- Targets: Several subcortical nuclei, dependent on disease (e.g. subthalamic nucleus), which are relatively precisely addressed.
- Stimulus parameters: monopolar cathodic square pulses (1-5 V amplitude, 60-200 ms duration, 120-180 Hz frequency), usually derived in a trial-and-error process.
- Mechanism on cellular level is unclear.
- Chirurgical intervention is relatively safe. Local chirurgic intervention for battery change (after several month, dependent on stimulation)
- Patient may control stimulator to some extend



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# DBS – Applications (1)

## General notes:

- Historical roots: mid 20th century (Penfield, Delgado)
  - Today's technology has been developed in the 1980s, first for the therapy of movement disorders (Parkinson, Dystonia, etc.)
  - Up to end 2006: more than 35'000 patients are equipped with DBS (Hardesty & Sackeim 2007)
  - In the last few years, further applications have been tested in experimental studies:
    - Alzheimer (memory enhancement)
    - Anxiety disorders
    - Autism
    - Depression
    - Epilepsy
    - Multiple sclerosis
    - Obesity
    - Obsessive-compulsive disorders
    - Tourette syndrom
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# DBS – Applications (2)

## **Problems discussed in the scientific literature:**

- Generally: good results for pharmaceutically resistant movement disorders.
- DBS failures (for movement disorders) are mainly caused by misplacement (48% of cases).
- Sudden “on-off-effects” appear, as well as changes on a longer timescale (several weeks to months, indicating lack of knowledge on physiological mechanisms).
- Dispute on increased suicide-risk (Burkhard et al. 2004; Albanese et al. 2005; Foncke et al. 2006).
- Dispute on validation of „quality-of-life“ after intervention (Diamond & Jankovic 2005).
- Anecdotic reports on complex behavioral changes in patients.

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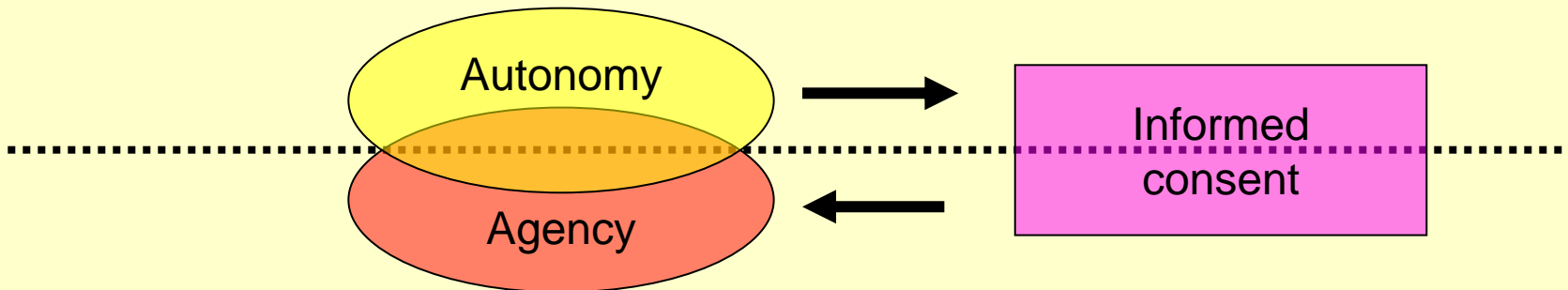
# Autonomy & agency: concepts

- Autonomy:**
- Reflected decision-making („space of reason“)
  - Higher order thoughts (second order volitions)
  - Development of a personality
  - Social competence (relational autonomy)
  - (- Determinism vs. free will)

- Agency:**
- Perception → decision making → action
  - Goal-oriented inner states
  - Interaction with other agents
  - Reactive behavior / learning
  - (- Embodiment)
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# Autonomy, agency & informed consent

Normative  
level



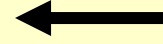
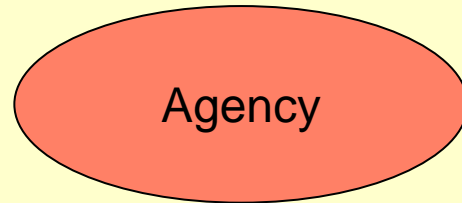
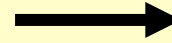
Empirical  
level

→ *Autonomy as a prerequisite of informed consent.*

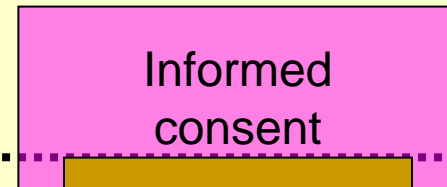
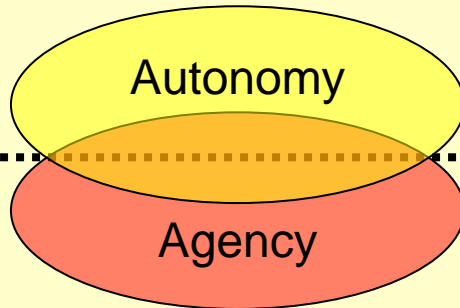
→ *Informed consent as an expression of agency.*

# Autonomy, agency & DBS

Movement disorders



Psychiatric disorders





# Agency, autonomy & DBS: propositions (1)

## Can DBS improve autonomy and agency?

*The optimistic philosopher:*

**Autonomy:** Yes!

- allows for 2nd order volitions (e.g. avoiding depression, intrusive thoughts) and thus augments of decision-making capacity
- allows for lucid (instead of disordered) states of mind, thus allows for ex post justification of some interventions (informed consent ex post).

**Agency:** Yes!

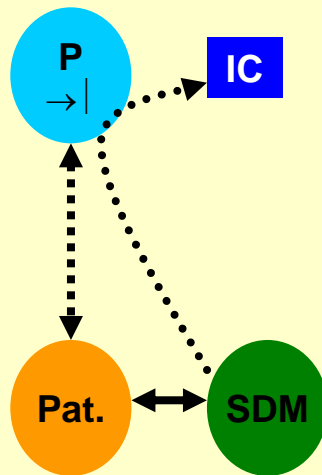
- Movement disorders: Tremor is gone
- Psychiatric disorders: Allows for active life

# Autonomy, agency & DBS: propositions (2)

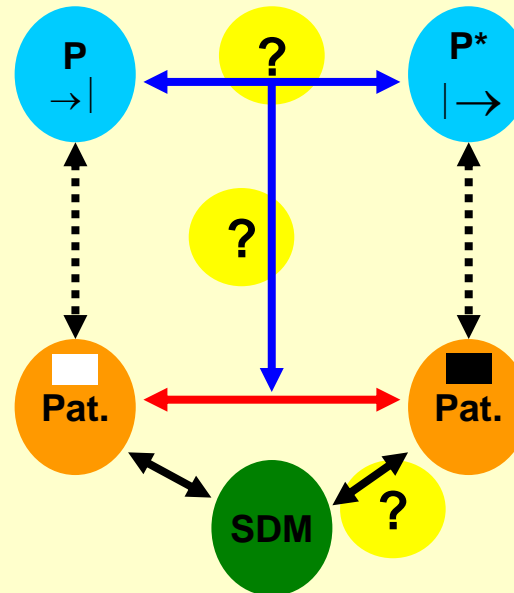
## Can DBS improve autonomy and agency?

*The skeptical philosopher: skeptical of the clear separation between the empirical and normative levels in psychiatric disorders.*

Before intervention



After intervention



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**Thank you!**

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