

# BIOETHICAL CONSIDERATIONS OF EMERGING MEDICAL INTERVENTIONS FOR OCD

IOCDF Conference - San Francisco, CA  
Friday, July 7, 8:00-9:30am PT



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# Disclaimer

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This talk is not eligible for CE credit.

# OVERVIEW

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- Principles of Bioethics
- Overview emerging biomedical interventions for OCD
- History of ethical violations in neurosurgery & medicine
- Psychedelic medications, neurostimulation and neurosurgical treatment options for OCD
- Ethical considerations specific to pediatrics, genomics and cutting-edge research

# 4 GUIDING PRINCIPLES OF BIOETHICS

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- Autonomy
- Beneficence
- Nonmaleficence
- Justice



# PRINCIPLES IN CONFLICT

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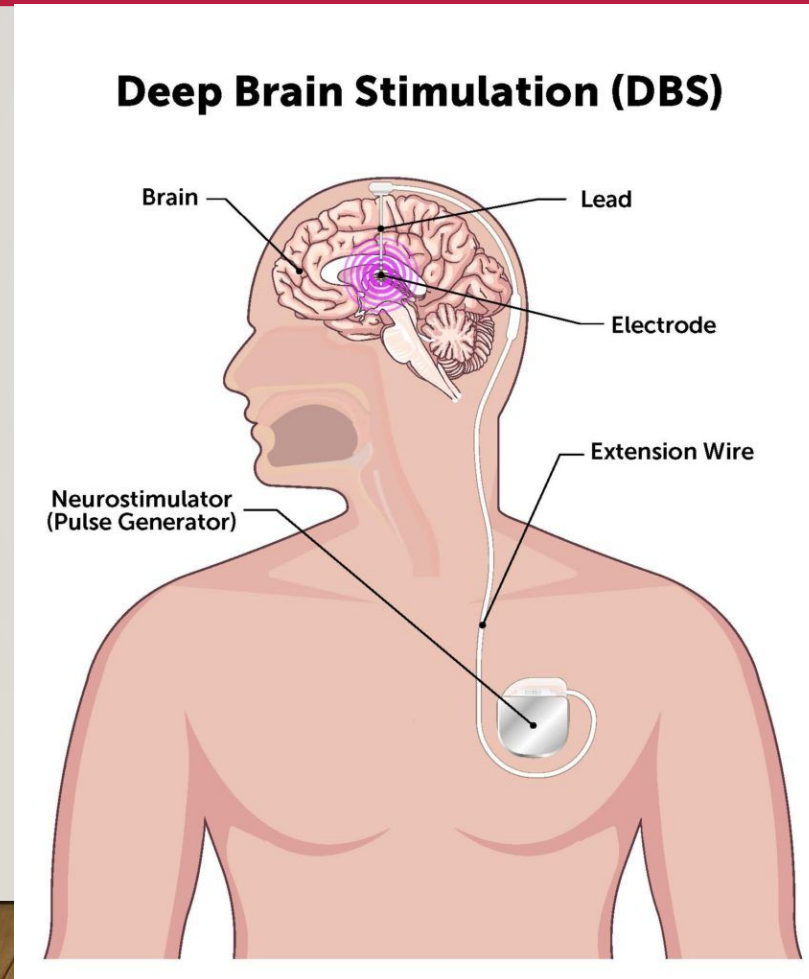
- Do the risks outweigh the benefits?
- Who is eligible for treatment? Who has access to treatment?
- Who has the power to decide?
- Who benefits (or profits) most from advancing these interventions?
- What are possible long-term implications or repercussions of these interventions?
- How do these interventions influence public perception, stigma?

# EMERGING BIOMEDICAL INTERVENTIONS FOR OCD

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- Deep brain stimulation (DBS)
- Transcranial Magnetic Stimulations (deep=dTMS; repetitive=rTMS)
- Transcranial Direct Current Stimulation (tDCS)
- Ablative neurosurgery, Gamma knife
- Experimental medications: e.g., ketamine, psilocybin
- Genetics: polygenic risk scores (PGS)

# DEEP BRAIN STIMULATION (DBS)



# GAMMA KNIFE (RADIATION)

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# TRANSCRANIAL MAGNETIC STIMULATION

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# PRINCIPLES IN CONFLICT

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# DEEP TRANSCRANIAL MAGNETIC STIMULATION (dTMS)

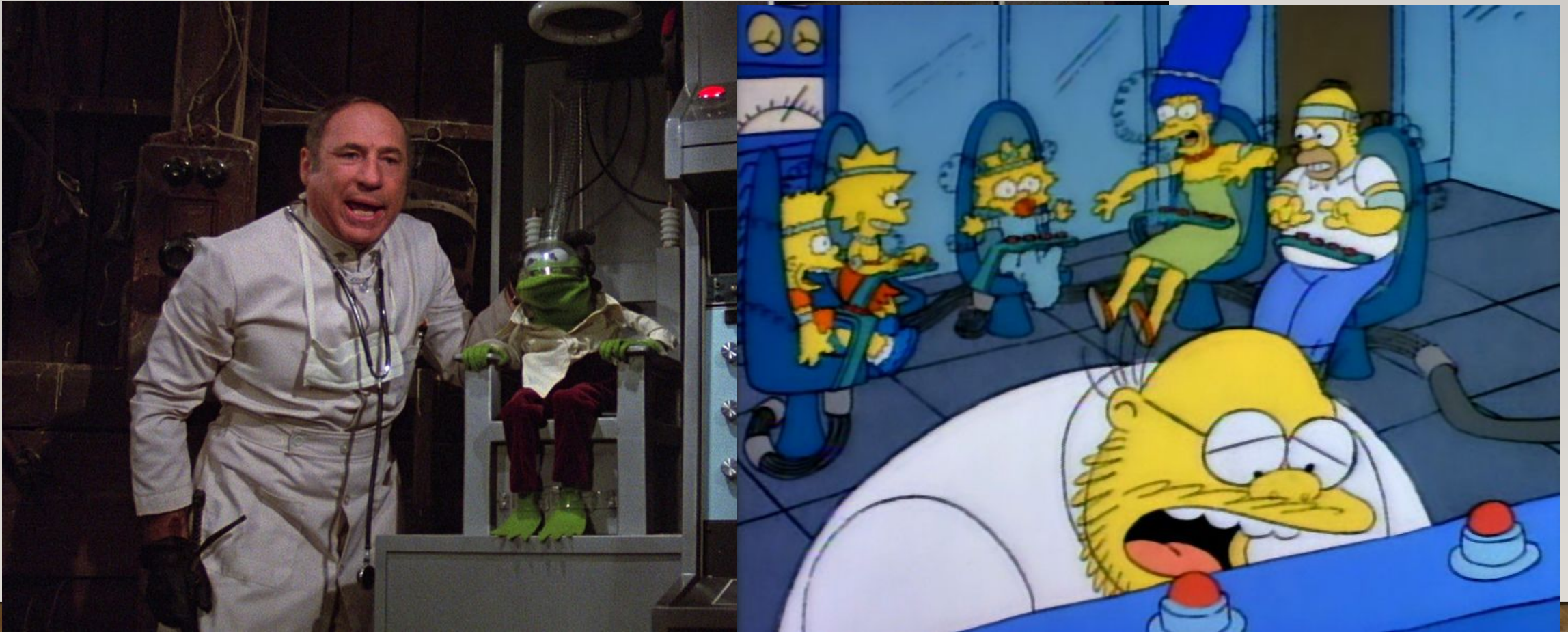
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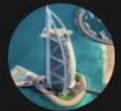
# CONCEPTS & IMAGES OF NEUROMODULATION IN POP CULTURE

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# YOUTUBE: DBS FOR OCD COMMENTS



**zahi hmi** 1 year ago

I need this surgery

32 [REPLY](#)

[View 6 replies](#)



**Влад Мішин** 2 weeks ago

it's kinda scary if they do that surgery that means that ERP not that affective

[REPLY](#)



**Sh E** 5 months ago (edited)

I can't trust this at all!! Remember 50 years ago the lobotomy process, how it ruined lives of many people and how even it killed people. No, no, no... brain is so complex a surgery can't solve all problems like that, and it might give you even more problems, depriving you from basic brain functioning!! It's so scary...

10 [REPLY](#)

[View reply](#)



**B** 9 months ago

OCD is effecting my life

12 [REPLY](#)

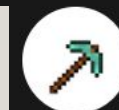


**lincee Sen** 8 months ago

Plzzz i need this surgery toooo...plzz help mee...i want to live my life,i cn't tolerate it anymore 🥺🥺🥺🥺🥺🥺

6 [REPLY](#)

[View 4 replies](#)



**Fahid** 3 months ago

Modern day lobotomy

2 [REPLY](#)

# Ethics in Psychiatry and the Clinician/Educator

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Robert Hudak MD

Associate Professor of Psychiatry

University of Pittsburgh School of Medicine



# NEUROSURGICAL INTERVENTIONS

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- Why are ethics particularly important in this area?
- Let's go back in time to talk about the beginnings of this field
- Trigger warning: graphic descriptions of medical procedures will be discussed

# LOBOTOMY FOR MENTAL ILLNESS

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- The leucotomy was invented in 1935 by a Portuguese neurologist named Antonio Egas Moniz.
- Others had tried types of lobotomies in the past, but he discovered a new method
- The procedure is described as horrific today, but the alternatives were equally as horrific back then



# LEUCOTOMY

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- Procedure involved drilling two holes in the skull and then using ethanol initially and then a wire loop to sever the connections between the frontal lobes and the rest of the brain
- He had a surgeon perform the procedure
- He reported success with the first 20 patients
- However, his evaluation, data-gathering and record keeping were poor

# ENTER WALTER FREEMAN

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- Medical profession was initially hostile to leukotomy, but then Moniz met Walter Freeman, a US neurologist, by chance at a conference
- Freeman was sold, and while initially did procedures with a neurosurgeon, he eventually decided that he could do it on his own.
- Freeman toured the U.S. doing lobotomies in institutions everywhere, wearing flamboyant clothes, and often doing 2 procedures at the same time with each hand

# LOBOTOMY TOURS

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- However, Freeman stubbornly stuck to the procedure while it was abandoned by virtually everyone else
- He expanded the reasons for doing this to almost any indication and performed it on children as young as 4 years old.
- Consent rarely given, and Freeman's follow-ups were sloppy to non-existent
- Last performed in 1967

# BUT LET'S NOT JUST PICK ON PSYCHIATRY EITHER

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- Tuskegee
- FAS
- Thalidomide

Many of the ethical problems that have occurred in medicine were overseen by the everyday clinician



# RISKS/BENEFITS

Relative to: 1) another procedure/intervention or 2) NO procedure/intervention

## RISKS

- Adverse Events - brain hemorrhage, infection (DBS), Seizure risk (TMS)
- Irreversible procedures (ablative)
- Destructive (ablative)
- Unclear effectiveness/guidelines (all)
- Cost

## BENEFITS

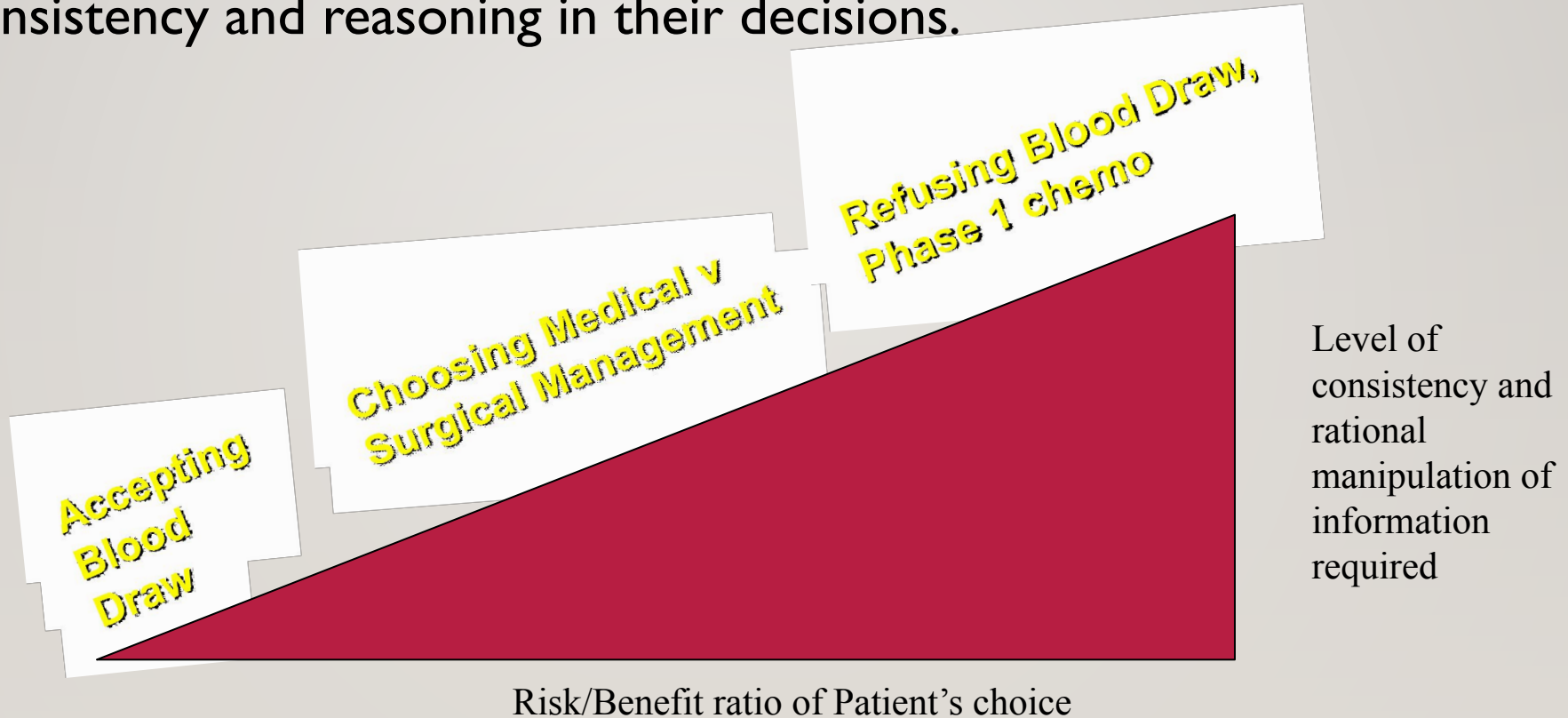
- Possibility of symptom reduction
- Hope for refractory cases
- Reversible (to an extent)
- Non-destructive (TMS, DBS)
- Adjustable

# INFORMED CONSENT

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- Does the patient have the capacity to make this decision?
- Does the patient fully understand the risks and benefits?
- Are patient expectations in line with the likely outcome?
- Is the patient/family under and undue pressure or duress?

- Decisional Capacity is evaluated on a sliding scale based on the risk/benefit ratio of the patient's choice versus standard care.
- The larger the difference in risk, the greater the requirement for consistency and reasoning in their decisions.



# NEUROSURGICAL INTERVENTIONS FOR OCD

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Three different informed consents for neurosurgical OCD procedures:

Approved with consensus:

- Deep Brain Stimulation
- Ablative neurosurgery

Approved without guidelines:

- dTMS



# NEUROSURGICAL PROCEDURES

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- How appropriate are patient referrals?
- What is patient criteria?
- 2 out of 325 people referred meet criteria for surgery  
(Garnaat et al 2014)

# OCD Research and OCD Teaching as a Clinician/Educator

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- Many of the patients I refer for my research studies are my own patients. What obligations do I have to ensure that they do not feel their clinical care is at jeopardy if they do not choose to participate?
- Are referrals to IOCDF (where I was in charge funds) a conflict of interest? What is in the best interest of my patients?
- What are the ethical obligations involved in teaching residents about OCD and psychiatry in general? Is teaching “the facts” enough? What about staying current?
- What are the ethical obligations in teaching other members of the medical profession at large, particularly in a field in which so much is done “off- label”?

# Research into Ethics of Neuromodulation

**Eric Storch, PhD**

**Professor & McIngvale Presidential Endowed Chair**

**Vice Chair & Head, Psychology**

**Department of Psychiatry & Behavioral Sciences**

**Baylor College of Medicine**

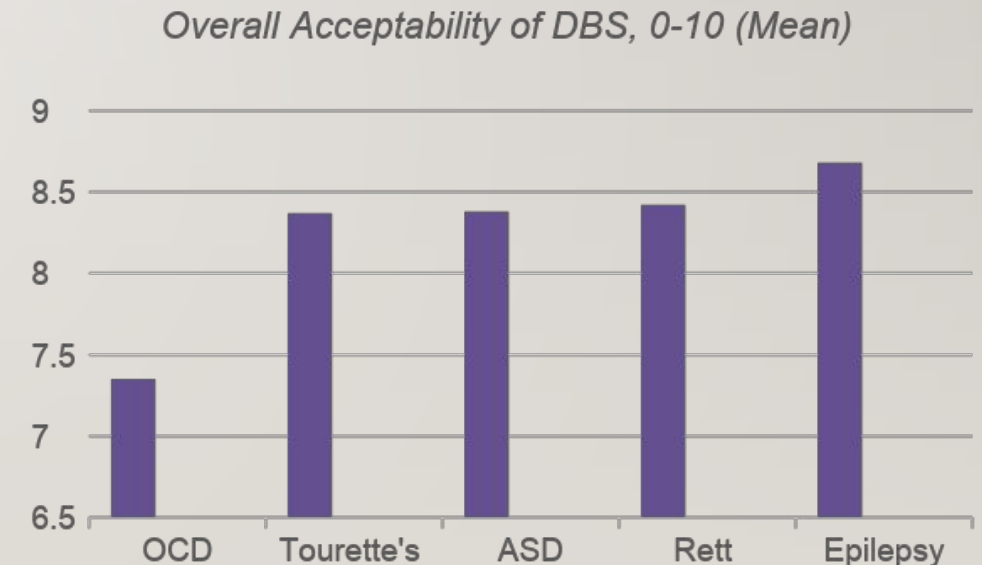
**[Eric.storch@bcm.edu](mailto:Eric.storch@bcm.edu)**

**Baylor**  
College of  
Medicine®

# PARENTAL ATTITUDES TOWARD DBS IN ADOLESCENTS WITH TREATMENT-RESISTANT CONDITIONS (STORCH ET AL., 2019)

- 279 parent participants
- Favorable impressions of DBS across conditions
  - Especially if:
    - Greater improvement assured
    - Child had capacity to assist in the decision
- Some reluctance to use DBS when possible safety concerns present
- Pre-existing knowledge of DBS significantly predicted acceptability of DBS for Rett syndrome, ASD, epilepsy

- Ratings of acceptability lower for OCD compared to other conditions assessed





# PERCEPTION OF DBS IN ADOLESCENTS WITH OCD

(WEINZIMMER ET AL., 2021)

- 260 parents of children with a history of OCD and adults with a history of OCD.
- More willing to consider DBS for epilepsy than for OCD.
- Factors associated with greater willingness to consider DBS:
  - Familiarity
  - Presence of suicidal thoughts
  - Assurances of daily functioning improvements and substantial symptom reduction.
- Concerns about safety, personality changes, and long-term effects on the body were associated with greatest reluctance.

TABLE 3. FREQUENCIES OF ACCEPTABILITY RATINGS OF DEEP BRAIN STIMULATION FOR SEVERE, REFRACTORY ADOLESCENT OBSESSIVE-COMPULSIVE DISORDER (N= 199)

	<i>Endorsement frequency (%)</i>
0—Totally unacceptable	7 (3.5)
1	4 (2.0)
2	7 (3.5)
3	7 (3.5)
4	5 (2.5)
5—Neutral	19 (9.5)
6	24 (12.1)
7	41 (20.6)
8	44 (22.1)
9	16 (8.0)
10—Totally acceptable	25 (12.6)

# NEUROETHICS OF PEDIATRIC DBS (IRFIMH121371-01)

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## PURPOSE

- Examine the **neuroethical issues** surrounding use of pDBS.
- Examine **decisional needs** of stakeholders: clinicians, caregivers, and patients.
- **Develop a decision aid** to enhance SDM and improve collaboration.

## UNIQUE ETHICAL ISSUES

- Unknown impact of DBS on **personal identity** in developing children.
- Appropriateness of DBS for disorders that **may remit by early adulthood**.
- Potential need for **pDBS safeguards and protections** in the best interests of the child.
- Navigation of the **complex shared decision-making process** between minor patient, the caregiver who acts as surrogate decision maker, and the clinician.

# PARITY FOR DBS

- DBS therapy for OCD is often denied because “experimental and investigational” but is not for dystonia

Medical necessity criteria for the use of DBS for refractory OCD\*.

Chronicity	OCD Diagnosis for duration of at least 5 years	
Severity	Y-BOCS $\geq$ 28	
Functional Impairment	In at least one of the domains of: activities of daily living; social functioning; occupational functioning; thinking, concentration, and judgment; or ability to engage in other major life areas (3,4)	
Treatment-refractoriness	Persistence of severe symptoms (Y-BOCS $\geq$ 28) despite:	<p>Adequate trials (of at least 12-weeks in duration) of three serotonergic medications at FDA-maximum approved dosages or greater (one of which must be clomipramine)</p> <ul style="list-style-type: none"> <li>• The requirement for clomipramine may be excluded if the patient experiences adverse effects, does not tolerate the drug, or its use is otherwise contraindicated.</li> </ul> <p>The use of adjunctive pharmacological agents including a long-acting benzodiazepine and an antipsychotic.</p> <ul style="list-style-type: none"> <li>• The requirement for a benzodiazepine may be excluded if the patient has a history of substance use disorder or another contraindication to benzodiazepines</li> </ul> <p>Engagement in exposure therapy for at least 20 sessions with a clinician experienced in the treatment of OCD</p>



## Restriction of Access to Deep Brain Stimulation for Refractory OCD: Failure to Apply the Federal Parity Act

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# EXTENDING BEYOND NEUROMODULATION

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# POLYGENIC RISK SCORES IN CHILD AND ADOLESCENT PSYCHIATRY SURVEY

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3R00HG008689

## SIGNIFICANCE

- The identification of these genomic loci makes it possible to generate polygenic risk scores (PRS) to stratify an individual's risk for different psychiatric disorders.
- The usual age of onset for most psychiatric disorders.
- The promise of reliable PRS in mental health care and prevention is considerable, but there are critical potential ethical and policy challenges.

## PURPOSE

- Identify child and adolescent psychiatrists' knowledge, practices, attitudes, expectations, and perceived benefits and risks about the use of psychiatric PRS.

# POLYGENIC RISK SCORES IN CHILD PSYCHIATRY: ETHICAL, CLINICAL AND LEGAL IMPLICATIONS

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- Develop ethically-justified and empirically-informed guidelines to address the ethical challenges raised by the use of psychiatric PRS with children and adolescents.
- Employ a mixed-methods design to examine: 1) ethical challenges in the clinical use of psychiatric PRS, 2) key stakeholders' perspectives on psychiatric PRS, and 3) gaps in legal protections and potential solutions.
- **Aim 1: Examine the experiences and perspectives of CAP who have managed psychiatric PRS.**
- **Aim 2: Examine the perspectives of patients and caregivers toward the use of psychiatric PRS.**
- **Aim 3: Identify and examine gaps in legal protections against privacy violations and discrimination based on psychiatric PRS.**

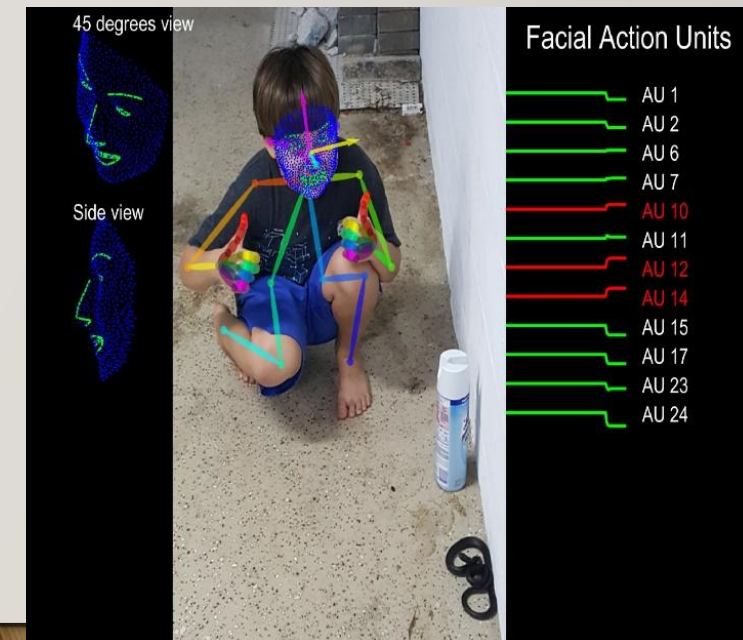
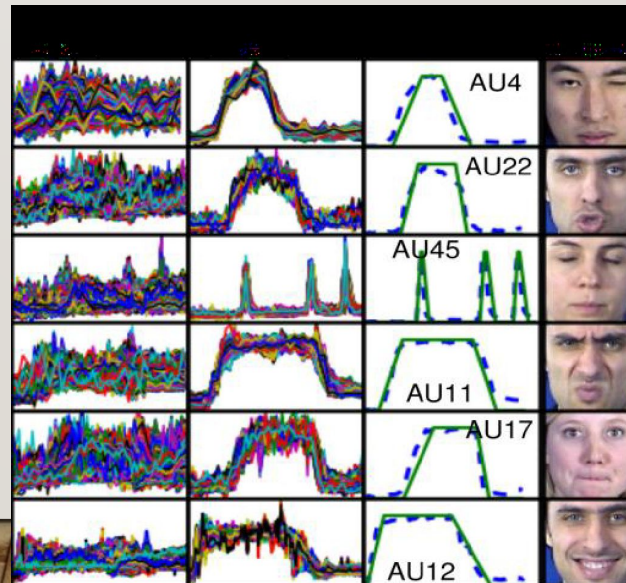
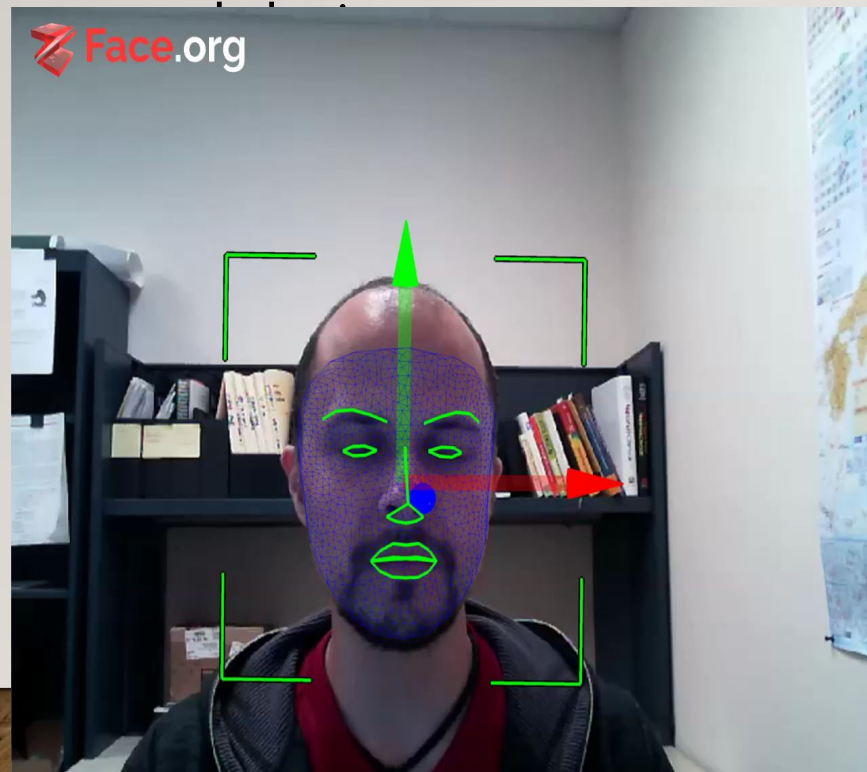


# OPTIMIZED AFFECTIVE COMPUTING MEASURES OF SOCIAL PROCESSES AND NEGATIVE VALENCE IN YOUTH PSYCHOPATHOLOGY

## R01 MHI25958-01 (MPI: HERRINGTON & STORCH)

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- Generate and validate objective, transdiagnostic, behavior-based Social Processing measures using facial expressions (i.e., face valence, facial expression synchrony) and vocal





# WHERE DO WE GO FROM HERE?

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- Most people watching this are OCD specialists or experts in some professional capacity
- What ethical responsibilities stem from our expertise?
- How can we work together to ensure the highest ethical standards guide the treatment of OCD?