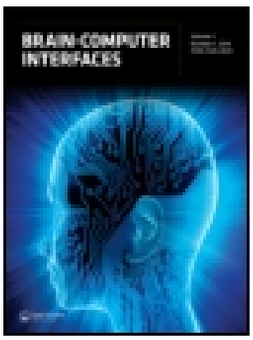

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Brain-computer interface-based control of closed-loop brain stimulation: attitudes and ethical considerations

Eran Klein[a,b]*, Sara Goering[a], Josh Gagne[c], Conor V. Shea[d,e], Rachel Franklin[d,e], Samuel Zorowitz[d,e], Darin D. Dougherty[d,e] and Alik S. Widge[d,e,f]

[a]*Center for Sensorimotor Neural Engineering and Department of Philosophy, University of Washington, Seattle, WA, USA;* [b]*Department of Neurology, Oregon Health and Science University, Portland, OR, USA;* [c]*Survey and Data Management Core, Dana-Farber Cancer Institute, Boston, MA, USA;* [d]*Division of Neurotherapeutics, Department of Psychiatry, Massachusetts General Hospital, Boston, MA, USA;* [e]*Department of Psychiatry, Harvard Medical School, Boston, MA, USA;* [f]*Picower Institute for Learning & Memory, Massachusetts Institute of Technology, Boston, MA, USA*

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Patients who have undergone deep brain stimulation (DBS) for emerging indications have unique perspectives on ethical challenges that may shape trial design and identify key design features for BCI-driven DBS systems. DBS research in cognitive and emotional disorders has generated significant ethical interest. Much of this work has focused on developing ethical guidelines and recommendations for open-loop DBS systems. While early trials of open-loop DBS for depression gave disappointing results, research is moving toward clinical trials with closed-loop or patient-controllable DBS systems that may modulate aspects of personality and emotion. Though user-centered design is an increasingly important principle in neurotechnology, the perspectives of implanted individuals on ethical issues raised by DBS are poorly understood. We solicited those perspectives through a focus group and set of qualitative interviews of participants in trials of DBS for depression and obsessive-compulsive disorder. We identified four major themes: control over device function, authentic self, relationship effects, and meaningful consent. Each has implications for the design of closed-loop systems for non-motor disorders.

Keywords: deep brain stimulation; ethics; closed-loop; patient-controlled; end-user perspectives

Introduction

Deep brain stimulation is a potential therapy for treatment-resistant psychiatric disease. It has undergone formal clinical trials in major depressive disorder (MDD) [1, 2] and obsessive compulsive disorder (OCD).[3] Smaller trials and case series have proposed the use of DBS for addiction, eating disorders, and major neurocognitive disorders.[4–7] MDD is a leading cause of disability, affecting approximately 14.8 million American adults, with a lifetime prevalence rate of 19.2%.[8] OCD affects 3% of the world's population.[9] Medications and psychotherapy are the most common treatments for psychiatric disorders, but these treatments fail to alleviate symptoms in a substantial fraction of patients.[10, 11] Deep brain stimulation (DBS) has been investigated as a potential treatment option for refractory MDD and OCD. While open-label studies of DBS have shown success in MDD and OCD,[12–14] two large randomized trials of DBS in MDD failed, while the results of a randomized OCD trial are not yet published. DBS for OCD remains available under a Humanitarian Device Exemption (HDE) in the United States and a CE mark in Europe.[15]

Recent advances in brain-computer interface (BCI) technology allow recorded brain activity to modulate neurostimulation. Together with a growing understanding of mental disorders as fluctuating circuit-based illnesses, this has led to proposals that DBS for complex psychiatric diseases like MDD and OCD should emphasize 'closed-loop' systems in which embedded algorithms automatically adjust stimulation parameters to match a patient's clinical need or to achieve a brain electrophysiologic state that correlates with 'wellness'.[16–20] The core theory is that psychiatric illnesses are heterogeneous, and likely contain multiple neurobiological entities within each formal disorder.[15, 19, 21] To achieve a clinical response, it would be helpful to identify how a patient's brain activity is uniquely different from a large sample of healthy controls, then titrate stimulation to minimize that difference. Related approaches have shown preliminary success in Parkinson disease.[17, 18] Moreover, unlike the relatively fixed deficits of a motor-system disease, psychiatric symptoms can fluctuate substantially within or between days. Open-loop DBS, which delivers treatment at a fixed dose, may lead to over-treatment. This may explain common side effects such as hypomania.[22] While these potential advances are appealing to clinicians and researchers, it is not known whether they are aligned with patients' desires and interests.

*Corresponding author. Email: kleineuw@uw.edu

The growing use of open-loop DBS for neuropsychiatric disease in the last decade generated significant ethical interest.[23–28] Psychosurgery has a controversial history, and DBS echoes many of the same concerns, particularly related to patient autonomy and informed consent. Ethical guidance has been offered on matters of conflict of interest,[29] ethical and regulatory oversight,[30] decisional capacity,[24] subject selection,[30] and responsible experimental and publication practices.[24] Development of ethical guidelines and recommendations has relied heavily on informal clinical and research experience of experts within the field of DBS and limited data from a qualitative survey of neurosurgeons.[31]

Formal assessment of end-user perspectives has not generally been a prominent part of developing ethical guidelines and recommendations for psychiatric DBS. One group studied participants considering enrollment in a study of DBS for depression.[32, 33] Using the MacCAT-CR instrument, the group found that 31 potential entrants into a DBS trial for depression retained decision-making capacity despite depression, though they showed a high incidence of the therapeutic misconception (i.e. subjects believed that they would *personally* benefit from participation in a randomized trial).[32] A European group conducted a study of 18 individuals who had received DBS for OCD.[34] They interviewed participants about effects of DBS beyond those captured in typical depression, anxiety, and quality of life scales. For instance, they found an increase in trust, self-reliance, and self-confidence among DBS responders. These findings suggest that physicians may not always recognize the complexity of the responses patients have to DBS. They also indicate that those responses have been inadequately studied and documented, particularly in forums for neurotechnology researchers.

Moving to closed-loop or patient-controlled DBS will raise new ethical issues not confronted when psychiatric DBS was first proposed. A system that employs BCI-like technology to decode a patient's emotional state comes much closer to 'mind reading' than existing motor BCIs. The internal data from such a system could be damaging if compromised. Beyond privacy concerns, brain-data recording facilitates novel forms of neuromodulation. If a closed-loop controller is added, one has effectively constructed a device that autonomously determines what the patient may or may not feel. This raises substantial concerns about patients' self-determination, and both patients and society may see such devices as a threat to human autonomy.[19] On the other hand, if a patient is given control over device settings, the temptation to increase stimulation settings to feel better and better may be difficult to resist, and patients may fear the introduction of a new kind of addiction.

This next stage of research should be more explicitly shaped by patient experience. While closed-loop or patient-controlled systems have characteristics that are theoretically attractive, there is no documented evidence that patients desire them. Patients may have ethical concerns that preclude closed-loop approaches. Studying patients' experience with psychiatric illness and DBS affords the opportunity for a critical check on the ethical guidelines and theoretical concerns that generated so much interest in the early stages of open-loop DBS research. Empirical data on the experience of actual users could identify whether current ethical guidelines are sufficient or need amendment. In an era of increasingly expensive research and limited dollars, devices should be built to satisfy actual patient needs and ethical concerns. End-users can provide unique insights that physicians alone cannot generate. We therefore sought to make those insights more readily available to the neural engineering community, by documenting psychiatric patients' experience with open-loop DBS and their thoughts about proposed closed-loop designs. This information would likely be valuable to researchers proposing new closed-loop systems in this area.

We conducted a qualitative study of 15 subjects implanted with DBS for depression or OCD at Massachusetts General Hospital (MGH). We interviewed individuals for their perspectives about closed-loop or next-generation DBS devices, given their experience with open-loop DBS. We found that four major themes characterized their attitudes toward next-generation DBS: control over device function, authentic self, relationship effects, and meaningful consent. These attitudes about closed-loop DBS can inform future development of psychiatric DBS research.

Methods

Recruitment

Participants were recruited between June and December 2015. Participants were eligible if they had received a DBS system as part of a clinical trial for MDD or OCD and were tracked in a registry maintained at MGH. This included patients whose devices had been implanted at other hospitals. Recruitment targeted all patients tracked in the registry, which included patients with both good and suboptimal clinical response, and included patients whose devices had been explanted or turned off. Eligible subjects were contacted by telephone and mail. A research coordinator discussed risks and benefits of participation and answered questions. Participants who were able and willing to travel to Boston were enrolled in a focus group. Individuals for whom travel represented a hardship were interviewed individually by phone. The study protocol was reviewed and approved by the MGH

Institutional Review Board. All subjects in this study had DBS at the ventral capsule/ventral striatum (VC/VS) target. An overview of the neurobiologic rationale for the VC/VS target, patient selection criteria for MDD and OCD, and surgical targeting procedure is available.[35–37]

Data collection

The focus group was conducted with eight participants at MGH in the summer of 2015. The group was moderated by one of us (SG). The moderator was an educator with extensive experience teaching and facilitating small group discussion of ethics topics. The focus group was 90 min long and audio-recorded for later transcription. Individual one-on-one interviews were conducted with an additional seven participants. A trained interviewer (JG) conducted the interviews after observing the focus group to ensure consistency of facilitation between focus group and individual interviews. Interviews were approximately 30–60 min long and, like the focus groups, audio-recorded and transcribed for analysis. An interview guide was prepared by all members of the team for use in both the focus group and individual interviews. The guide used a multi-step hypothetical case of an individual considering a closed-loop DBS device (Supplemental material). The components of the hypothetical case invited participants to consider the following topics: responsibility, identity, privacy, security, and enhancement, and to expand on these as they felt appropriate.

Analysis

The transcribed interview data were analyzed according to a conventional qualitative content analysis method, [38–41] which was composed of a two-stage coding process: Level 1 structural coding and Level 2 thematic coding. Structural coding follows the structure of the focus group guide, hence every question received a structural code that is applied to the appropriate text. Thematic coding was based on emergent themes that arose from review of the structural coding, and were applied in a second-pass analysis. These methods are enhanced by the use of N'Vivo (v.10) software (QSR International). The program uses an organizer indexing system for coding, categorizing, searching, retrieving, attaching analytical memos, and creating conceptual relationship networks in textual data that have been taxonomically coded. After the two-stage coding process was completed, a comprehensive thematic analysis summary report was produced.

Results

Profiles of the participants (Table 1)

Emergent themes

Four major themes emerged from the analysis of focus group and key informant interviews, capturing areas where patients had either substantial concurrence of opinion or a marked disagreement (Table 2):

- *Control over device function*: types of control over DBS device settings and risks and benefits of control.
- *Authentic self*: capability of a DBS device to allow expression of authentic self.
- *Relationship effects*: impact of DBS on relationships with family, medical personnel, and researchers.
- *Meaningful consent*: effective communication of complex information, framing of realistic expectations, and attention to cognitive and affective impairments.

Control over device function

Participants referenced their experience with open-loop DBS when offering their perspective on next-generation devices. They expressed optimism that subject-controlled and closed-loop technology could improve on certain limitations of open-loop devices. For instance, subjects found the trial-and-error nature of standard DBS programming very frustrating. They disliked the frequent clinic visits needed to make adjustments to device settings to optimize symptom relief. The uncertainty of achieving response (or how long response might last once achieved) was distressing to several subjects, and they expressed hope that a self-titrating system would reduce this uncertainty. Another attractive feature of next-generational DBS was the prospect of reducing comorbidity associated with battery depletion and replacement.

The prospect of volitional control over DBS settings elicited a range of responses. Some respondents were enthusiastic about subject control of stimulation, particularly if it more effectively overcame symptoms of depression or OCD. Most respondents, however, felt that they would not be entirely comfortable having sole or primary control over DBS settings, and preferred that control over device settings be left to clinicians. In part, the desire for clinician oversight or control was driven by a concern that subject-controlled DBS could lead to inappropriate or unhealthy uses of DBS. This was most commonly expressed as a concern for the addictive potential of patient-controlled DBS (F1, F2, F3, F4, KI1, KI2). '[I]t's kind of disconcerting to have something in your brain that's like, "Oh, you feeling bad? Here's you go, here's some drugs"' (F3). That said, not all

Table 1. Demographics.

Participant (F/I)	Age (decade)	Gender (M/F/O)	DBS indication (MDD/OCD)	Time since implant (years)
F-1	5th	F	MDD	5
F-2	6th	M	OCD	8
F-3	3rd	F	OCD	2
F-4	4th	M	OCD	0.5
F-5	5th	F	MDD	9
F-6	7th	F	MDD	9
F-7	7th	M	MDD	6
F-8	4th	F	OCD	2
I-1	6th	F	MDD	6
I-2	4th	M	OCD	4
I-3	3rd	F	OCD	3
I-4	6th	M	MDD	5
I-5	3rd	F	OCD	2
I-6	7th	F	OCD	0.5
I-7	3rd	M	OCD	0.5

F = focus group, I = interview, M = male, F = female, O = other, MDD = major depressive disorder, OCD = obsessive compulsive disorder.

participants felt that the risk of inappropriate use warranted prohibition (F1).

Authentic self

Participants reported that an attractive feature of DBS in general, and particularly if next-generation DBS proves more effective than current practices, is the opportunity to experience a more authentic self. This was reported in two ways. The first was the belief that depression masks who an individual is, in their own estimation or the estimation of others. A more effective DBS offers the prospect of lifting one out of depression so that the true self can reemerge. An alternative perspective on authenticity was expressed by respondents who felt that DBS freed individuals to become who they wanted to be. For instance, when DBS was felt to counter the decreased motivation or anhedonia of depression, respondents expressed that DBS could allow an individual to pursue goals and satisfy desires that the experience of depression precluded.

Some respondents, on the other hand, expressed that DBS might *undermine* a sense of self. This concern took two forms. The first was a concern that DBS might produce emotions that were artificial in some way. For instance, participants considered that someone might be able to 'game the system' – to turn on or turn up stimulation in a closed-loop system by purposely bringing a sad memory to mind. Most respondents thought that this was inauthentic or artificial, and therefore inappropriate. The second form of this concern was a worry that individuals with DBS might lose track of their sense of agency if it became unclear whether they or the device was responsible for their feeling or acting in a certain way. Respondents expressed that this concern would be amplified in patients who receive closed-loop systems, if the system maintained them in a relatively constant state of subjective well-being, and prevented them from experiencing a 'normal' range of emotion (e.g. feeling sadness at a funeral).

Relationship effects

Respondents indicated that next-generation DBS could affect their relationships with others, and that open-loop DBS often had already had such effects. A common concern was that next-generation DBS might exacerbate what respondents currently experienced as a shifting of blame to them or the functioning of their device, with family or others pointing to the device as the reason for experiencing an undesirable emotion. Several respondents felt that family members became too quick to point to the device as a *solution* to residual symptoms or interpersonal disagreements, directing the patient to get his or her settings checked or altered. Others felt that next-generation DBS might have no effect or a positive effect on their relationship with others, particularly if it could more effectively treat psychiatric symptoms.

Respondents also felt that DBS could have positive effects on relationships with clinicians and researchers. This was most commonly described in terms of developing trust in their clinician or research team, such as around collection of sensitive data (KI2) or ensuring protection from device hacking (KI4).) In addition, many respondents indicated that DBS trial participation required extending the traditional subject-researcher relationship beyond the formal conclusion of the study (F1, F2, F6, F7, KI1, KI2, KI4). Participants felt that researchers undertaking next-generation DBS trials had obligations to provide medical care, expertise, and equipment (batteries) to subjects beyond the completion of study.

Table 2. Emergent themes.

Control over device function	
Opinions on closed-loop DBS	'There'd probably be less trial and error.' (KI5) 'Pretty much just tunes itself … you don't need to see a doctor every … three weeks to turn it up.' (KI7) '[DBS device] would have backed off enough that [the battery] would have lasted.' (F5)
Opinions on direct patient control of DBS	'Any progression in getting somebody through this. You know, that's just … incredible' 'You could get rid of that feeling just by, you know, flipping a switch or, or thinking something specific, it would be hard not to do that in the moment. It seems like a dangerous kind of precedent.' (KI2)
Preference for clinician control over settings	'I wouldn't want to tweak the setting. You can only fine-tune it, I think, so much, as far as controlling emotions. I'd be afraid that you'd tweak it one way, and that it makes somethin' else get screwed up.' (F5) 'I think it should be treated like medication … it's not up to the patient what medication prescription meds they take, so … I think it should be treated like medication.' (F3) 'I would say that the doctor HAS to have the final say on any kind of adjustments … not the patient.' (KI2)
Authentic self	
Returning to one's true self	'Back to sort of a baseline … back to yourself.' (F2) 'Access parts of myself that gave me enjoyment, that I wasn't able to when I didn't have the surgery.' (KI3) 'Feel more like yourself.' (KI6) 'Go back to the more authentic you.' (KI7) 'I still like the same things. I don't have, like, different values or anything. I just enjoy things more. I'm me without depression.'.(F3) '[Others] see, like, the person I was, like, when I was young. I mean, I'm obviously more mature, but they see more of the authentic me. Like, "I've got my son back".' (KI7)
Freedom to construct a new self	'People tell me that they didn't know that I was under there. That I'm entirely different. They didn't know I had such a wide range of affect, or that I was so much fun, or whatever, and I know that when my DBS system is working at its best, I'm aware of having feelings that I never knew existed before.' (KI1)
Ambiguous agency	'I've begun to wonder what's me and what's the depression, and what's the stimulator.' (KI5) 'There are parts of this where you just wonder how much is YOU any more, and you wonder kind of, "How much of it is my thought pattern? How would I deal with this if I didn't have the stimulation system?" You kind of feel artificial.' (KI4) 'Your feelings don't get attributed to YOU. They're all due to the device.' (KI1) 'So, there's people in my family that sometimes question, you know, how much of it is me any more and how much of me is, you know, bein' programmed. So that's been a, that's a hard thing to deal with sometimes.' (KI4)
Relationship effects	
Change interpersonal dynamics	'You might not know who I am now when I get this all fixed up. Are you still gonna love me?' (F1) 'I feel like I now have a much more healthy and normal mother to son … relationship than before.' (KI5)
Others interpret sadness as device malfunction	'The first question some people have for you, even people that are very close to me, is: "Did you check your system? Are you okay?" So, that, that's a pretty hard thing to deal with because we're all struggling just to be the best we can. And then to think that somebody's thinkin', "Well, you know what? Your battery's not charged fully enough so you need to go charge". You know? That that's a pretty hard thing to deal with ….' (KI4) 'If things are bad, and I'm feeling bad about what's going on at home, [my father's] solution is always to get it turned up, "Why can't you get turned up? … Yeah, just because there's, like, a little candyman in your head, I don't have to be nice to you, I just have to turn it up and you'll be OK with me yelling at you." And so it gave him an excuse … he's actually been worse since I've had it … it's funny – I'M better, he's WORSE!' (F3).
Device adjustment as easy solution	'I think there's this expectation which I find with my family, that, if you're not feeling well, go flip a switch and you'll be better.' (F2) '"Go get your settings adjusted!" That's [my family's] answer to EVERYTHING!' (F7)
Meaningful consent	
Perceived effects of depression on understanding	'Mine [depression] was so bad that my mom had to do all of the reading for me, just had to trust her. I could not read to save my life.' (F3) 'When you have depression, you can't pay attention, you can't comprehend.' (F5) 'I was in such a dark place that if I heard [about the follow-up], I would have been like, "No. No".' [F3]

(*Continued*)

Table 2. (*Continued*)

Perceived effects of depression on appreciation of risks	'I could have cared less about the risks' (KI6) 'I was so depressed I didn't even care. I was, "Whatever!" You know?' (KI7)
Desperation	'I mean, I was missing months of work, I was in a Mass General mental health facility and other mental health facilities around the state. I just didn't know what to do!' (F6) 'I didn't really have a choice. I really didn't. It was so bad. I really didn't have a choice.' (KI1) 'I'm willing to try anything. I'm not … like, I'm not even afraid if it's got a 50% chance of death, I'll still try it 'cause I'm so desperate, and I'm … I'm suffering so much.' (KI7) '[With] severe depression, you'll do anything to get out of it!' (KI6) 'The people that will still be ready to sign up are the ones who truly are, are desperate, and who feel like this is sort of the last resort.' (KI2)
Unrealistic expectations	'I think when you're at that point, you're just hoping for the moon. I think most people have unrealistic expectations.' (KI1) '[T]hat desperation, it does make them vulnerable to kind of unrealistic expectations … I don't think anybody is going to undertake something as, as serious as a brain surgery without believing that it was going to have a … a tremendous beneficial impact.' (KI2)

Meaningful consent

Participants felt that consent was very important to research trials involving DBS, but pointed to a variety of issues with giving consent in this context. All individuals provided consent for their own participation in a DBS trial, but many of them reported difficulty understanding and fully appreciating the relevant risks reported on the consent form. Partly this was an issue of the complexity and novelty of DBS technology, and the difficulty of predicting all the relevant risks in advance. Participants also expressed concern about the ability of individuals with treatment-resistant mental illness to consent to DBS research. Some of this concern related to a belief that mental illness interferes with the ability to understand information presented or to appreciate the risks involved in research. An additional concern was that the hopelessness felt by individuals with treatment-resistant mental illness could affect the consent process. This could both amplify therapeutic misconception and cause patients to over-weight the potential risks or burden of follow-up appointments. Some respondents recalled their own sense of desperation when considering enrolling in a DBS trial.

Discussion

This qualitative study examined the perspectives of individuals with implanted DBS devices on the prospect of future closed-loop technology for treatment of psychiatric illness. Four major themes emerged from this study: control over device function, authentic self, relationship effects, and meaningful consent. These findings provide a basis for incorporating the concerns, needs, and values of end-users into the next phase of BCI-based neurostimulation devices.

As BCI-based principles and technology are incorporated into clinical interventions, such as DBS for psychiatric disease, it is critical that researchers and clinicians adopt an approach of user-centered design.[42, 43] While groups have begun to collect data on BCI users or potential users, most attention has focused on gathering feedback on technical obstacles to device adoption, such as set-up, maintenance, ease of use, comfort, and aesthetic features of devices,[43–46] rather than on ethical obstacles. Researchers believe that ethical obstacles are important [47] and some groups have explored these in wearable BCI,[48] but minimal data have been gathered from actual end-users with implanted BCI or other neurostimulation devices.[34] The current study contributes to this needed literature, particularly with respect to ethics trade-offs.

Despite some important worries about authenticity, we found a general optimism about BCI-based DBS and a frequent willingness to trade feeling better most of the time (i.e. reduced depression compared to open-loop DBS) for the risk of emotional blunting. Given concerns in the literature about potential detrimental effects of DBS on authenticity,[49–52] the willingness of actual end-users of DBS to contemplate this trade-off is revealing. At least one participant, however, withdrew their openness to closed-loop DBS after thinking more about issues of authenticity and identity. This suggests that ignoring issues of authenticity and identity in the next-generation device design would be unwise, even if many individuals might be desperate enough to give up some autheniticity in favor of feeling better. Furthermore, the concern for the addictive potential of closed-loop systems and the preference for clinician oversight (if not strict control) of stimulation parameters, rather than patient control, was a surprising finding. How patients want to apportion control over their BCI systems vis-à-vis their physician – and how this may affect the traditional patient-clinician relationship as a result – are important areas for future research.[53]

Meaningful informed consent is a central tenet of neurostimulation research, but obstacles exist to full realization of this ideal. Chief among these is the

therapeutic misconception: the belief that a study participant will personally benefit from study participation.[54] Despite physician and clinician awareness of and attention to this issue in neurostimulation research,[32] subjects in this study expressed a clear heightened concern for therapeutic misconception. Besides the therapeutic misconception, subjects identified risks of participation in neurostimulation research not typically included in consent processes: loss of cognitive privacy and alterations to identity or sense of self. Though these non-traditional risks have been hypothesized as of particular relevance to consent to BCI research,[55, 56] the current study provides important empirical support.

The role that family plays in the decision to volunteer for BCI-based neurostimulation research and its ultimate success appears underappreciated. We found that family could be significant drivers of the decision to enroll in neurostimulation research. We also found that misunderstandings by family members about the function or effectiveness of implanted devices could have detrimental relationship effects. An implanted device can be blamed for a wide range of undesired outcomes (e.g. patient and family conflict) and can be looked to as a quick-fix solution to any problem. The development of BCI-based closed-loop systems may exacerbate these tendencies. Implantable devices may successfully alleviate symptoms but in turn lead to a burden of normality if well-established patient-family roles are disrupted.[57] The family and caregiver perspectives on neurostimulation research and their role in patients' recovery is underexplored and would benefit from increased attention.

Based on our findings, we offer the following preliminary but important recommendations:

(1) Closed-loop DBS should be explored for cognitive and emotional disorders, as individuals with open-loop DBS systems for cognitive and emotional disorders broadly found the prospect of closed-loop DBS attractive, despite some recognizable drawbacks.
(2) As these BCI-based closed-loop systems are developed, researchers should seek early input from users of existing systems.
(3) Informed consent processes should be tailored to the specific capabilities and risks of BCI-based systems. This should include:
    a. Improving disclosure and exploration of potential atypical risks (e.g. privacy, identity).
    b. Inclusion and robust education of surrogates or patient advocates when possible. This should include expectation-setting regarding the limits of DBS-like therapies.
    c. Special efforts to recognize and address the therapeutic misconception, such as by measuring unrealistic optimism.[58]
(4) Developers of closed-loop algorithms should recognize that patients' interest in trading control for clinical efficacy spans a wide range, which may allow use of a broader range of approaches.

Our findings and recommendations should be understood within the limitations of the study. While 14 patients is a large sample for DBS, all participants were recruited from a single academic medical center, giving us little information on how patient-physician relationships affect perceptions. We hope that our work will spur similar studies in other large cohorts, which may clarify and extend these findings. Many of the individuals knew little about closed-loop technology beyond the information provided in the focus group and interviews. The interviews and focus groups were conducted by two different members of the research team, and though both used a jointly developed interview guide and attempted to maintain uniformity in conduct of the interviews and focus group, it is possible that different facilitators led to differences in responses. Closed-loop strategies often have nuances unfamiliar to non-technologists, and we were not able to fully investigate erroneous prior beliefs or assumptions that subjects may have. This would also be a fruitful topic for further research. That said, this population, given first-hand experience with DBS, is more likely than others to appreciate unknown risks of novel technology, and thus offers a critical perspective.

Conclusion

Patients who have lived with implantable open-loop devices for mood and anxiety disorders have unique perspectives on the ethics and desirability of proposed closed-loop, BCI-based DBS systems. They can see the benefit of such systems and generally seem willing to accept the trade-offs that might accompany them. These trade-offs are ones that device designers may not expect. The availability of closed-loop devices may also place greater burdens and expectations on recipients, if friends and family expect them to be constantly calm/happy. These themes are already emerging with open-loop devices as the implanted population expands, and likely can be more effectively managed by engaging early with the patient/user community.

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ORCID

Josh Gagne http://orcid.org/0000-0001-8580-1533
Darin D. Dougherty http://orcid.org/0000-0003-4691-4353
Alik S. Widge http://orcid.org/0000-0001-8510-341X

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