Letter: Commentary: Deep Brain Stimulation as Clinical Innovation: An Ethical and Organizational Framework to Sustain Deliberations about Psychiatric Deep Brain Stimulation

Joseph J. Fins (Commentary: Deep brain stimulation as clinical innovation: An ethical and organizational framework to sustain deliberations about psychiatric deep brain stimulation)[1] takes issue with our proposal to guide ethical thinking about the potential use of deep brain stimulation (DBS) as a form of clinical innovation in the context of psychiatric conditions.[2] Clinical innovation falls neither squarely in the category of therapeutic usage nor research usage and is therefore not well covered by customary clinical ethics or research ethics paradigms respectively.[2-5] As we point out, this gray zone maps to a well-recognized area of clinical practices and includes a broad range of clinical innovations such as off-label uses of pharmaceuticals and adaptations of established surgical procedures to individual patients with specific clinical needs. Unfortunately, Fins[1] confuses clinical innovation with research and thereby misapplies a research ethics paradigm to clinical innovation. We take this opportunity to clarify a number of misunderstandings about and misrepresentations of our proposal.[2] Importantly, contrary to the claims attributed to us, we make no blanket recommendations for or against the use of DBS as a form of clinical innovation; rather, we appropriately leave this analysis to be done on a case-by-case basis. Our aim is actually to highlight the ethical considerations involved in undertaking such an analysis.

Fins[1] suggests that our proposal "leaves our ethics behind by calling for innovation outside of usual regulatory oversight."[1] Nowhere do we call for activities outside the purview of usual regulatory oversight. Rather, our focus is on an area (clinical innovation) that lies precisely at the interstice between 2 distinct regimes of regulation and professional oversight (clinical practice and research).[2-5,6] Consequently, we explore the relevant ethical oversight for this distinct context. It is therefore highly misleading to claim that we call for any "neurosurgical exceptionalism,"[1] which implies removing neurosurgery from the requirements of common clinical and research oversight. Ironically, it is Fins who calls for exceptionalism and argues that neurosurgery should fall under a separate regime, again because he conflates clinical innovation with research activities.[1] We respond that neurosurgeons should not be prevented from pursuing clinical innovation, since other clinicians (and their patients) have that option. It is worth pointing out that clinical innovation has long been a part of the history of functional neurosurgery, and is arguably the mechanism by which lesioning procedures—such as cingulotomy and capsulotomy—are offered to patients with severe psychiatric illness.

Fins takes issue with arguments in favor of self-regulation[1] although it is clear that he again has in mind the research context that he describes as involving an "investigative team" and "deep brain stimulation research."[1] Should we have such a research context in mind, we would agree with most if not all that Fins recommends. However, this is again not the context at hand. Our recommendation is that clinicians and institutions consider special forms of review for clinical innovation because there is evidence that some clinical innovations are not properly and independently reviewed.[7,8] This recommendation is not driven by a desire to "decrease administrative burden"[1] and by no way changes the requirements applicable to research activities. Accordingly, we are not calling for "localizing regulation within an institution"[1] since there is scant applicable regulation that could be delocalized. In fact, there exists a panoply of approaches currently in use to evaluate the clinical and ethical merits of an innovative surgical procedure such as peer oversight, surgical innovation committees, governmental oversight, or falling back on existing clinical ethics committees or institutional review boards (reviewed in Karpowicz et al[6]). The overwhelming majority of commentators agree that falling back on the "standard research paradigm" as Fins proposes can, for different reasons, jeopardize clinical innovation and will thus remove this option for surgeons and their patients.

Fins argues against our focus on the primacy of patient's wellbeing in justifying clinical innovations, notably because DBS has not been shown to be an unequivocally efficacious treatment in research settings.[1] Clearly, Fins has again in mind the research context where an "investigator" would be breaching "clinical equipoise"[1] and other canons of research ethics. We actually take for granted that an innovative procedure may be proposed in absence of an ongoing research trial for the patient to join. This is certainly the current reality for patients with intractable psychiatric illness. That being said, standards for informed consent for clinical innovation must remain stringent and this is exactly what we argue for and where the literature clearly stands.[9] Accordingly, the caution against an emphasis on the "novelty" of the procedure[10] is not to prevent the patient from being informed as insinuated by Fins but rather, on the contrary, to ensure that the patient's consent to an innovative surgery is not swayed unduly by the attractiveness and novelty of the procedure which needs to be presented to the patient as experimental and unproven.

We hope readers will trust that we by no means call for exceptionalism to existing research ethics requirements with our proposal for a framework to assess ethical aspects of DBS-based clinical innovation. Quite the contrary, we provide a framework to shed light on the ethical gray zone of clinical innovation which exists between clinical practice and research activities. In our eyes, and contrary to Fins, we see no reason to make an exception against clinical innovation in the domain of

psychiatric DBS such that it would have to be considered automatically a research activity. This is exactly the kind of ethical paternalism that we think Fins would be opposed to. As medicine and society have evolved, so has the earlier protectionist paradigm of bioethics, which has given way to a more participatory paradigm that engages patients as autonomous individuals.[11] We would however reiterate that all proposals for the oversight of surgical innovation, including ours, should be evaluated for their clinical and ethical outcomes, something that to our knowledge has not yet been done.[6]

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