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Desperation May Affect Autonomy but Not Informed Consent

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Dunn and colleagues (2011) provide an interesting analysis of the ethical issues involved in deep brain stimulation (DBS) for people with treatment-resistant depression (TRD). I agree with the conclusions the authors draw regarding TRD patients' capacity to consent but would like to take up the authors' call for greater examination of the way in which desperation may affect patients' decision making about research participation. I propose that desperation affects not capacity to consent but voluntariness and that any attempts to explore desperation should reflect this.

In the context of informed consent, voluntariness is legally defined in relation to external constraints imposed by others, in forms such as coercion, undue influence, force, or fraud (see, e.g., Jackson 2009). Other accounts of voluntariness, however, acknowledge the role of circumstances. Roberts (2003) has previously argued that illness-related factors and psychological issues, among other things, may affect the voluntariness of decisions. Likewise, Nelson and Merz (2002) note that threats to voluntariness can arise from potential participants' vulnerabilities, while Hewlett (1996) specifically criticizes the informed consent model for failing to address the influence of circumstances on consent to clinical research participation. Patient circumstances may of course include the nature of their illness and any feelings of desperation that their condition creates. These accounts are supported by a definition of voluntariness provided by Olsaretti (1998). Olsaretti makes a distinction between free choices and voluntary choices, arguing that they are not necessarily related but are often confused with one another. Choices should be termed *free* if they are not subject to the influences of other people. Choices are *nonvoluntary*, however, if they are made because no other option is acceptable to a person in terms of that person's well-being other than the option ultimately chosen. Choices are voluntary when there is an acceptable alternative or when, even if there is no acceptable alternative, the only option available is chosen because the agent likes it and would choose it even if another acceptable option also existed. Olsaretti gives an example of nonvoluntariness, as follows:

> Daisy lives in a city surrounded by desert. She desires to leave, but knows she would not survive the journey through the sands, and therefore chooses to stay. Daisy is free to leave—nobody prevents her—but she acts non-voluntarily, since she stays only because all other possibilities would be fatal. (Olsaretti 2004, 138–139)

If we apply this notion of voluntariness to the health care context, it may be the case that a patient can only make a voluntary choice to participate in research if more than one acceptable option is available to her. Otherwise, as Hewlett notes, her choice is merely theoretical. Thus, if the choice a desperate patient faces is between undergoing an experimental treatment, or declining and accepting the lack of effective standard treatment for her, the decision to enrol in a trial may seem the only acceptable option. The decision may be a competent one, fully informed and even free, but it may not be voluntary. Dunn and colleagues

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consider whether desperate patients lack genuine autonomy in some way, even if they cannot be presumed to lack decision-making capacity; Olsaretti's notion of voluntariness appears to provide an explanation of the specific way in which the desperate patient's autonomy may be impaired without implicating capacity.

In order to address concerns about desperation, however, Dunn and colleagues propose the use of instruments assessing patients' attitudes to research and its risks and benefits in order to strengthen the process of informed consent. If such an instrument is to tap into the concept of desperation, the crucial question to ask potential research participants, based on the account of voluntariness just given, is whether they feel they have any acceptable alternative other than to say yes to entering a trial when it is offered, and whether they would have declined the trial offer if such an alternative had existed.

If Olsaretti's definition of voluntariness is accepted, however, the ability of the desperate patient to give consent, as it is presently defined, may not technically be affected, even though the voluntariness of the person's decision making might be. There is also the question of what action recruiting researchers should take in light of the information gathered from such an instrument. Dunn and colleagues propose a more thorough consent process, which is always to be commended. However, while detailed attention to the information and comprehension aspects of informed consent may indeed help to correct misperceptions or misplaced expectations, this process is unlikely to be able to assuage the desperation that may drive a patient to undergo an experimental intervention even when fully and accurately informed about significant risks and uncertain benefits and in possession of the cognitive capacity to make such a decision. Agrawal (2003) states that it is important to characterize ethical concerns correctly in order to apply the appropriate safeguards. For desperate patients, as with other vulnerable individuals, if a particular aspect of autonomy cannot be enhanced at the consent level (and is not even incorporated into the consent concept in the case of Olsaretti's definition of voluntariness), the key safeguard may lie at a different stage of the research process. Agrawal believes that vulnerability is more useful as a term if one defines what a person is vulnerable *to*. In the case of a research trial, certain patients may be vulnerable to *exploitation*, i.e., vulnerable to accepting an unfair distribution of the risks and benefits of the research. Potentially exploitative offers should of course be addressed by the ethical researcher at the trial design stage, but the appropriate safeguard against exploitation, Agrawal argues, is ethics committee review to ensure that *any* patient invited into a trial is offered a fair balance of risks and potential benefits if the person participates. This is not simply a matter of equipoise but also of providing a "fair deal" within each trial group (since two trial groups may be equally "unfair" and still satisfy equipoise). Even the desperate patient who finds a trial offer irresistible should not, therefore, be faced with a poor risk/potential benefit ratio that exploits that person's desperation. As Resnik (2002) argues, "There is nothing inherently wrong with conducting research on subjects that suffer from . . . misfortunes or vulnerabilities, provided, of course, that one does not take unfair advantage of those subjects" (2002, 29). Resnik's conclusion accommodates Dunn and colleagues' legitimate concerns that to exclude desperate patients from research is to ignore the ethical principle of justice.

In summary, I argue that while the relationship between TRD and consent may be explicated in terms of capacity, desperation may have its effect on voluntariness (as defined by Olsaretti) rather than on capacity and that its effect may be difficult to ameliorate through informed consent measures. Since my commentary is also a theoretical exploration of the issue, I support Dunn and colleagues' call for more empirical research into the relationship between desperation, autonomy, and research participation. ■

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