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Dementia research and advance consent: it is not about critical interests

Karin Rolanda Jongsma, Suzanne van de Vathorst

Tom Buller presents a rich and thoughtful proposal for using advance directives in the context of research.[1] He argues that the arguments presented in support of advance directives within the context of treatment also count within the context of research. Furthermore, he argues that research participation can be a critical interest and, therefore, continues to exist during the process of dementia, and furthermore, that a critical interest should overrule experiential interests, e.g, the experience of burden, during the research trial. We appreciate his contribution to the debate on advance directives and agree with his general claim that advance directives in the context of dementia research are valuable. However, we disagree with the statement that research and treatment do not differ significantly. Moreover, we argue that labelling research participation a 'critical interest' is too strong a claim for most people. We will provide more convincing arguments for the use of advance research directives and suggest how the value of advance research directives should be understood in practice.

Buller is right in arguing that it is a pity advance directives are not used more frequently within the context of research. Research with people who suffer from dementia is important and we should search for morally acceptable means to increase the research opportunities in this group. Biomedical research, however, differs not just gradually, but fundamentally from the treatment context, because of its aims: the main aim of treatment is to benefit the patients, whereas the main aim of research is not primarily to benefit the research participants, but to generate knowledge. Buller does not acknowledge this significant difference between treatment and research, stating:

> It is true that by its very nature research is inquisitive and that neither researcher nor participant can know for sure what the research will show or fully anticipate what might occur; but one can equally claim that the patient and the physician do not know what a future with dementia will be like or whether future treatments will be discovered.

We acknowledge that the epistemically opaqueness of research is a necessary condition for research, as research is aimed at developing new knowledge. However, we strongly question whether the epistemically opaqueness of treatment provides a justification for the opaqueness in the research context. We argue that precisely because of the fundamental uncertainty of its effects on the research participant, the research context needs to be bound by specific research guidelines.

Autonomous authorisation, or informed consent, is an important cornerstone and a legal prerequisite for research participation, because the research participant needs to be able to weigh burden and risks against her willingness to contribute to the research goals.[2 3] While for treatment in some cases the will of the patient may be overruled, it is never allowed to include a research participant in a trial without his consent. The main problem with performing clinical trials on populations unable to give adequate consent, such as patients with dementia, is that they are not (fully) capable of deciding whether they want to participate in research projects and what levels of risk and burden they find acceptable. This is problematical in the research context because possible therapeutic effects alone (beneficence, as Buller calls it in his article) are not enough reason to justify research participation. Authorisation is necessary, even if it is likely that a trial will benefit the participant; this underlines the difference between research and treatment. At the same time, conducting biomedical research with these populations is necessary to develop proper treatments for them. Given the gradually progressive nature of dementia, a patient with dementia has the opportunity to anticipate his future incompetence. One of the possible ways to anticipate this could be by consenting to research participation using an advance research directive. The moral power of advance directives is derived from the principle of respect for the patients (precedent) autonomy[4–6] and would be a valuable tool to provide autonomous authorisation beyond one's decision-making capacity.

Buller describes two interesting cases in his article. He describes the advance directive directed at the end-of-life decision of Mary and the advance research directive of William. Buller argues that the end-of-life decision of Mary as a critical interest is comparable with William's critical interest in research participation. He argues, in line with Dworkin, that because critical interests are based on the person's beliefs and convictions, they remain to have authority in case of contradictory experiential interests. His argumentation in the article is clear; however, we question his claim that research participation should be understood as a critical interest. Whereas it is imaginable that many people will have strong ideas about a life worth living, we find the case of Mary, who refuses to be treated once she is demented, reasonable and empirically plausible. However, the case of William having critical interests to be included in research seems less plausible. Having the 'desire to help' as a critical interest, wanting to participate in a trial at all costs, might be true for very few people, and even fewer will have such strong views regarding research participation. The analogy to the end-of-life decision based on Mary's critical interest is, therefore, not valid in our opinion.

There is also a pragmatic argument. In practice, a research participant who is unduly distressed or harmed or who expresses discomfort should be excluded from a trial. Research with a patient with dementia who clearly objects to research procedures that will not benefit him will be immediately stopped in practice.[7] This shows that experiential interests *do* count in the research practice. We argue that this is a desirable and ethical practice, as we should respect autonomous decisions and provide research participant with sufficient protection. Especially in the case of vulnerable populations such as patients with dementia, we should be extra cautious for any signs of undue harm to prevent any abuse or misconduct.

We, thus, argue against the assumption that research participation is a critical interest and against having these critical interests overrule experiential interest of demented research participants. A more

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subtle and precise approach is necessary to guide the use and moral status of advance research directives. Considering the status such documents have in practice and the attitude most people have towards future research decisions, we propose that these documents should rather be understood as 'a declaration of willingness to participate'. This document can then function as an authorisation to be included in a trial as advance consent. However, the ethical conduct of research is not over once there is a form of authorisation. Researchers should also take care of their participants' welfare during the trial. Protective measurements are especially necessary if the research population is physically and mentally vulnerable. Competent research participants have the right to withdraw from research at any time, and incompetent research participants should also have this opportunity. As incompetent participants are not able to change their mind about participation, they can only depend on others to protect their well-being during the trial and, therefore, should be excluded from research when they show signs of dissent.

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