The EANS Ethico-legal Committee finds the proposed head transplant project unethical

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Since the turn of the last century, head transplantation has captured the imagination of physicians, scientists and the general public. Recently, the procedure has regained attention as an Italian team has suggested to perform a head transplant in the near future. However, as pointed out by Lamba et al. [2], there are still many unanswered (technical, biological, ethical, psychological, etc.) questions related to head transplantation. The procedure is still highly experimental and should be considered clinical research. However, would it be ethical to perform such research at this stage?

In 2000, Emanuel et al. [1] published a hallmark paper on ethically sound research. They formulated seven requirements that will have to be fulfilled in order for research to be considered ethical. There is widespread consensus and most ethical committees will check for these seven requirements when reviewing research protocols. We will analyse whether these requirements are met for experimental head transplants.

The first requirement is that of value: the research should result in improvement in health or knowledge [1]. At this point, the work will not improve health as it is unlikely that the patient will obtain neurological function because of the procedure or even survive the procedure. It could be argued that the ability to perform a head transplant in, for example, a tetraplegic patient could at some point in the future be seen as “valuable”. Hence, the work can enhance our knowledge about the possibilities and limitations of head transplantation.

At the same time, one could argue that the organs of the potential donor of the body transplant, could be of greater use in many patients (instead of one) in need of an organ (heart, kidney, lung, etc.) transplant.

Second, the research should have scientific validity: the research must be methodologically rigorous [1]. For first-in-man procedures, there should be ample evidence from animal experiments and other models that all aspects of the procedure have been studied and that there are no remaining questions to be answered. As demonstrated in this issue of *Acta Neurochirurgica* [2], there remain many unsolved questions. There are no reports of head transplants performed in animals with long-term survival and normalisation of neurological function, and no evidence that all of the technical issues, such as functional cord re-anastomosis, can be successfully achieved in humans. Head transplantation at this stage does not meet the second requirement and for this reason we considered it unethical.

The third requirement for ethical sound research is a fair subject selection. This means that the inclusion criteria for individual subjects should be based strictly on scientific objections and on distribution of risks and benefits. It should not be influenced by factors such as vulnerability or privilege of the patient. Patients with severe neurological disease that might qualify for a head transplant will be very vulnerable and therefore the highest scientific and ethical standards in inclusion and oversight need to be adhered to.

Fourth, for research to be ethical there should be a favourable risk-benefit ratio. This means that within the context of standard clinical practice and the research protocol, risks must be minimised and potential benefits enhanced. The potential benefits to individuals and/or the knowledge gained for society must outweigh the risks [1]. The risks involved for the patient undergoing a head transplant is enormous, including this risk of death. There is no solid evidence

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base for all steps of the procedure; for some, there is even lack of proof of concept [2]. The risk-benefit ratio for a head transplant is currently extremely unfavourable. For this reason, we find it unethical. There is still much scientific development and proof of functionality needed for the individual steps of the procedure.

Fifth, there has to be an independent review. This requires unaffiliated individuals to review, amend, approve or terminate the research protocol. The goal of such a board would be to check for the seven requirements highlighted here, but also to see if there might be a potential conflict of interests. In the case of the proposed head transplant, ethical review is essential, as in all clinical research projects. The operation has been planned to take place in China, a country that has been criticised because of its less strict ethical oversight and regulation [3, 4]. Performing a head transplantation in a region with less strict ethical regulation will especially jeopardise the safety of vulnerable patients. We strongly advise that the Italian research group submit their research protocol to a European Ethical committee.

Sixth, there has to be informed consent; individuals should be informed about the research and provide their voluntary consent. The patient who will be selected for such a procedure will have to be informed and should voluntarily consent to the procedure. In case of the head transplant, informed consent should include not only the technical aspects of the procedure, but also that there is currently no knowledge about survival rate or evidence indicating improvement of neurological function. Moreover, it should be made clear that there is no pre-clinical evidence that suggests that a positive outcome will be likely and that there are major concerns in the scientific community.

In a patient population as vulnerable as this study population will be, the informed consent should be specifically designed and thoroughly vetted. Special emphasis should be paid to avoid overly positive outcome promises, which could result in therapeutic misconception.

Last, there should be respect for enrolled subjects. This includes protection of privacy, opportunity to withdraw, and monitoring of their well-being [1]. In the media there has been

a lot of attention for the patient who volunteered to be the first to undergo a head transplant. The privacy of this patient has been jeopardised even before official inclusion in the study. Given the nature of the proposed procedure, it will likely remain a challenge to protect the privacy of potential participants.

Nevertheless, it is an obligation for the team performing the procedure to try to protect it as much as possible. As for the opportunity to withdraw after the start of the procedure, there will be no true “exit” from the study possible for the patient. Before, after, and during the procedure, the well-being of the patient will need to be monitored. A detailed monitoring plan should be in place.

In conclusion, given the many safety and feasibility issues, proceeding with the head transplant is currently unacceptable. However, even if acceptable solutions are provided to all of the above-mentioned seven requirements, there are still numerous different and very fundamental ethical concerns—as for example, those related to personal identity and personhood. The Ethico-legal Committee of the EANS strongly advises against performing this procedure as proposed.

Compliance with ethical standards

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