Where Are We Heading? The Legality of Human Body Transplants Examined

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ABSTRACT: In this article the authors examine the legality of human body transplantation under the current state of medical knowledge. The article first analyzes under what conditions an experimental medical procedure may be legitimately performed under international and national law. Then it examines the legal requirements for prior ethics approval and considers the possible civil and criminal liability claims and disciplinary sanctions that may arise if such a procedure would fail. Subsequently, it applies this analysis to investigate whether body transplants would currently be legally allowed. The authors conclude that it is very unlikely that prior ethics approval would be obtained, and emphasize that physicians are likely to be found liable for medical malpractice if body transplantation is performed. If body transplantation results in the death of the patient, the physicians involved would run a considerable risk of being held criminally liable for negligent homicide. The participating physicians also risk severe disciplinary sanctions for professional misconduct, with a real possibility that they will be suspended or even banned from medical practice for life.

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Introduction

Despite major breakthroughs in the field of medicine, patients suffering from tetraplegia, progressive muscular disease or intractable cancer without brain metastases are left without any prospect of a cure. An audacious plan to help these persons by transplanting the torso of a brain-dead donor has recently been proposed by a medical team led by Italian neurosurgeon Sergio Canavero and Chinese orthopedic surgeon Xiaoping Ren.[1-4] In this article, we will examine whether, with the current state of medical knowledge, it would be legally and ethically acceptable to perform this procedure—often designated as "head transplantation," but more accurately described as whole body transplantation.

Medical experts and ethicists are highly skeptical about whole body transplantation.[5-7] They maintain that recipients would not be able to breathe independently or gain motor and sensory function over their new bodies because reattaching the cervical spinal cord is technically unfeasible. In addition, the recipients would run a very significant risk of developing post-surgical Central Pain Syndrome, a neurological disorder common after traumatic spinal cord severance and resulting in excruciating pain. Moreover, serious doubts are raised about the availability and the effects of the immunosuppression strategy needed to prevent the body from rejecting the recipient's head. Furthermore, even if the procedure were to be a partial success, the difficulties, which the recipient is likely to experience when integrating the neurological and chemical signals transmitted by the donor body, are likely to result in a completely disturbed body image and extreme mental problems. Last but not least, were body transplants to be allowed, they would raise unprecedented philosophical issues concerning the nature of the resultant person.[8-9]

In their eagerness to cross "the final frontier in transplant surgery," Canavero and Ren set these concerns aside.[10] They insist that body transplantation has become technically feasible through a combination of experimental approaches incorporated in their protocol, which would distinguish it from earlier attempts at body transplantation.[11-13] Canavero claims that his GEMINI spinal cord fusion procedure has been successfully demonstrated in animal studies and that he has developed a therapeutic strategy for Central Pain Syndrome.[14] Possible immune rejection would be countered by novel immunosuppressive protocols and, in order to prevent catastrophic mental problems, recipients would undergo psychological rehabilitation with the help of virtual reality and hypnosis.[15] With the feasibility of the procedure allegedly beyond any doubt, Canavero and Ren reject concerns over its ethical acceptability. In their view, the desperate situation of potential candidates for body transplantation, combined with the lack of therapeutic alternatives, make it imperative to attempt the procedure.

According to news reports, the transplant team aimed to perform the first body transplant towards the end of 2017 in China.[16] After this plan was first announced in 2016, Canavero and Ren seem to have been diligently working towards its execution. They have considerably expanded their medical team, centered their research and surgical preparation at Harbin Medical University, China, and are actively considering

Chinese volunteers.[17-19] More importantly, Canavero and Ren have begun testing their surgical protocols on rats. In resulting research papers, published in early 2017, they claim to have succeeded in reversing the paralysis attendant to a complete transection of the spinal cord and to have taken major steps in reducing brain tissue ischemia and increasing the possibility of long-time survival.[20-21] Although their conclusions were again disputed by top experts in the fields of neuroscience and neurosurgery—who questioned whether the spinal cord of the rats had been severed completely[17-19]—it is clear that the prospect that Canavero and Ren will execute their plan is taken seriously by the scientific community.

Considering that it seems to be increasingly likely that body transplantation will be attempted in the near future, an ethical and legal perspective on the issue is urgently needed. In this article, we will first analyze under what conditions an experimental medical procedure can be legitimately performed and what liability claims may arise if such a procedure were to fail. Subsequently, we will apply this analysis to investigate whether body transplants would currently be allowed.

The Legitimacy of Experimental Medical Procedures Under International Law and Ethical Guidelines

International ethical and legal standards on medical experiments were first developed in response to the atrocities committed in the Second World War. Crucially, the Nuremberg Code prohibits experiments on consenting participants "where there is a priori reason to believe that death or disabling injury will occur."[22] However, when death or disabling injury is not certain but still probable, experiments are not necessarily prohibited if they are performed on volunteers who otherwise face certain death. In this respect, the Declaration of Helsinki explicitly allows physicians to use an unproven intervention as a last resort option to save the life or alleviate the suffering of a consenting patient.[23] This exception has proven particularly important in the field of transplantation, where many of the major breakthroughs have resulted from experimental procedures.

The ethical permissibility of such experimental procedures under the limited circumstances described above is recognized in the World Medical Association (WMA) *Statement on Human Organ Donation and Transplantation*, noting that opportunities to conduct experimental transplant procedures should not be unduly curbed.[24] Similarly, international legal instruments that apply human rights to the health field, such as the UNESCO *Universal Declaration on Bioethics and Human Rights* and the Council of Europe's *Convention on Human Rights and Biomedicine*, underline the importance of respecting the autonomy of patients who consent to medical experiments. However, these interventions should only be carried out if they are in accordance with fundamental principles of medical ethics, medical practice and the professional codes of conduct. In this regard, from an ethical perspective it is crucial that the interests of physicians, scientists and the broader society in the outcome of the experiments should never take precedence over the interests of patients who would consider such a procedure.[25-26]

Additional requirements apply if the medical experiment is to be conducted within the research setting. The ethical and legal framework for experiments on human subjects are outlined in the *Declaration of Helsinki*, the *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, and the *Belmont Report*. The *Belmont Report* is of particular importance in that it was the first ethical guideline that clearly distinguished between clinical practice and human subjects research.[27] In experimental medical procedures, as in general clinical care, the goal of an intervention is to benefit individual patients and therefore any risk to a patient is intended to be offset by the expected benefit to the patients themselves. By contrast, in clinical research the goal is to produce generalizable scientific knowledge and only to minimize the risks which the research participant would assume in the interest of science. The *Belmont Report* emphasizes that these two goals ought to be clearly differentiated in order to achieve free and informed consent. If the two goals are conflated by researchers or patients, the latter may agree to participate in research on the incorrect assumption that the research interventions would constitute therapy. Alternatively, patients may understand that the intervention concerns research but may participate with the expectation that they would still benefit. This is known as "the therapeutic misconception," and leads to unjustified expectations and inadequate risk-benefit analysis on behalf of the patient and, consequently, may render the informed consent invalid.[28-29]

Moreover, the *Belmont Report* lays out a clear framework of three basic ethical principles that should be respected in the research setting. The principle of respect for persons dictates that individuals should be treated as autonomous persons, who should be adequately informed and not unduly influenced to participate in research. The principle of beneficence involves an obligation to protect individuals from harm and, where the level of harm would be deemed acceptable, to both minimize it and to maximize possible benefits. Finally, the principle of justice requires the fair distribution of burdens and benefits. The three principles outlined in the *Belmont Report* were subsequently codified in ethical guidelines and textbooks.[30-31] They were declared relevant to all interventions in the health field and have greatly influenced the framing of regulations.

On the basis of these principles, the *Belmont Report*, the *Declaration of Helsinki*, and the *International Ethical Guidelines for Biomedical Research Involving Human Subjects* stipulate that an experiment conducted within a research setting should be prohibited if it does not conform to generally accepted criteria of scientific quality or if the risks and burdens to the patient would be disproportionate to the expected benefits. Physicians wishing to undertake experimental procedures first have to obtain approval from an independent committee entrusted with the assessment of their scientific and ethical validity.[23,27,32] The relevant professional obligations are outlined in transplant guidelines such as the WHO *Guiding Principles on Human Cell, Tissue and Organ Transplantation* and the WMA's *Statement on Human Organ Donation and Transplantation*. In accordance with these international standards, experiments in transplantation may only be performed subject to the voluntary consent of the intended recipient, after the latter has been

informed about the purpose and experimental nature of the intervention, its risks and consequences, and possible alternatives.[24,33]

The Legitimacy of Experimental Medical Procedures Under National Law

The boundaries of acceptable medical experimentation have been defined by national legislation and case law on the basis of the aforementioned legal instruments and ethical principles and guidelines. Physicians risk civil and criminal liability and severe disciplinary sanctions if they perform experimental procedures that do not conform to these standards. Taking this into account, it is important to determine under what circumstances medical experiments would be allowed.

Prior Ethics Review

At the outset, the ethical and legal acceptability of a proposed medical experiment is to be examined during prior ethics review.[34] Ethics committees (when applied to the research context designated Institutional Review Boards in the US) will only approve the medical experiment if the protocol satisfies a number of requirements relating to consent, and risk and benefit. In the US, the applicable provisions are laid down in the Federal Policy for the Protection of Human Subjects, known as "the Common Rule," in the UK, in the Medicines for Human Use (Clinical Trials) Regulations 2004, and in China, in the Guidelines on Ethical Review of Biomedical Research Involving Human Subjects.[35-37]

For their autonomy to be respected, patients should be offered sufficient information to enable them to reach an enlightened decision. Because the level of disclosure is proportionate to the novelty and risks of the procedure, physicians would be required to inform willing patients about the highly experimental nature of the procedure.[38] The ethics committee should be satisfied that the disclosure allows patients to recognize fully the personal gamble that they would undertake. The ethics review also needs to ascertain that patients are legally competent and able to arrive at a reasoned decision. If the experimental procedure is an option of last resort, specific attention should be paid to possible impaired decision-making capability resulting from intense psychological responses of the patients to their incurable illness. In addition, desperate circumstances may make patients vulnerable to undue influence from the physicians who are proposing the experimental procedure.[39] If the experiment is primarily conceived as research, this should be clarified and properly communicated so as to prevent patients from falling prey to the therapeutic misconception.

Although the patient's consent is a necessary prerequisite, it alone cannot justify a medical experiment. Indeed, the main ethical and legal question is not whether the patient has consented but whether the experiment should be performed at all.[40] Therefore, the ethics committee should first be convinced that the risks of the procedure are reasonable in relation to its expected benefits. In weighing the risks and benefits of a medical experiment, the ethics committee has to ascertain that there is a reasonable

expectation that the experiment would be successful. The committee would have to be presented with evidence demonstrating that the proposed approach is scientifically plausible and clinically feasible. To that effect, proof should be provided that the experimental model has been validated in adequate laboratory settings and animal testing, and that it has the support of independent experts.[41]

Even if supporting scientific evidence can be presented, the ethics committee should refuse approval of an experiment if it is deemed unacceptably dangerous. Pursuant to the Nuremberg Code, this would be the case if there is *a priori* reason to believe that the experiment would result in death or a significant decrease in the patient's quality of life. Assuming that technical feasibility could be demonstrated and the experiment is not expected to result in death or a significant deterioration of the patient's health, an experiment will be deemed too hazardous if its risks cannot be adequately managed. Ethics committees therefore need to be satisfied that adequate risk management is in place.

The prospect of rapidly advancing disability and impending death may warrant greater flexibility in determining the acceptable risk-benefit ratio. However, this line of reasoning is sometimes misused so as to argue that a terminal illness would in itself legitimize whatever potentially therapeutic intervention the patient agrees to. Typically, it is argued that these patients have nothing to lose and should not be denied the possible benefit which may accrue from the experiment. However, patients may in fact have a lot to lose if they would be left in a more debilitated state than before. Moreover, terminally ill patients may find it psychologically very hard to refuse an alleged miracle cure. This would put them at great risk of being exploited when the proposed procedure is itself clearly inappropriate.[39]

In view of the potential for enormous benefits to large groups of future patients, it might be argued that consenting patients should be allowed to undergo a procedure even if the risks are high and major benefits to themselves are unlikely. However, this type of sacrifice for the greater good of science and society must be categorically rejected. As indicated above, international human rights instruments and ethical guidelines dictate that the welfare of the patient should always take precedence. This principle may hold even more strongly where terminally ill patients are concerned. If, as proposed by some authors, these patients should be considered a vulnerable population, then the possible advancement of medical science should not be given any independent weight in the risk/benefit calculation.[42] Moreover, it should be noted that the potential benefits of an experimental procedure should also be weighed against possible societal harms.[43] In the context of controversial and widely publicized medical procedures premature approval may undermine the integrity of, and public trust in, the medical profession.

If a medical experiment were to proceed without ethics approval, it is very likely that the physicians would be held liable retrospectively through tort liability and that, in extreme cases, they would face criminal prosecution. In civil law countries, body transplantation in the absence of ethics approval could even result in a direct cause of action for medical negligence and in criminal liability.

Civil Liability

If a medical experiment fails, patients or their next-of-kin can bring a medical negligence claim for compensation for possible injuries caused by the procedure. For such a claim to succeed, it is necessary to demonstrate that the physician breached a duty of care towards the patient, resulting in injury. Assuming that it can be shown that the patient has suffered injury, such as wrongful death or pain and suffering, the legal analysis would focus on a possible breach of duty and on causation. Actions in negligence can be brought either for failure to meet the standard of care in selecting and/or performing the medical intervention (so-called medical malpractice), or for failure to disclose information required for valid consent.[44]

In a claim for medical malpractice, the required standard of care is defined as being that of the ordinary skilled physician placed in similar circumstances. Physicians performing an experimental procedure are not negligent if their actions are endorsed by what is legally called "a responsible body of professional opinion." This implies that the court will have to consult distinguished experts in the field to determine whether the procedure could be a reasonable treatment option for the patient concerned. On the basis of this framework of negligence—which is broadly similar in common and civil law jurisdictions, including China[38,44-46]—it is generally accepted that, in the absence of a persistent minority opinion that finds in favor of the innovative procedure, the expert evidence supporting the treatment should be subjected to close judicial scrutiny.[47]

In line with the risk/benefit assessment that should have been undertaken during the prior ethics review, the court would then need to determine whether there was adequate pre-clinical evidential support for the plausibility and feasibility of the procedure, whether there was a convincing medical rationale for it, and whether the foreseeable risks were proportionate to the reasonably expected benefits. Greater risks would be justified when the patient was in a very serious condition, standard treatment was ineffective, and the patient had expressed a positive attitude towards a more innovative and risky therapeutic approach.[48-49] However, the idea that in such desperate circumstances anything would go does not stand up to judicial scrutiny since the experiment will always need to accord with the minimum standard of reasonableness outlined above.[50]

In addition to a claim in medical malpractice, an action may also be brought for lack of informed consent, when information essential to the patient's decision has not been disclosed. Historically, the applicable standard of care has been the same as the one governing medical malpractice, focusing on what a reasonable physician would have disclosed under similar circumstances.[51] Under that standard, patients should be informed about significant risks and possible alternative treatments, with higher levels of disclosure expected where physicians propose deviations from standard therapy.[44] However, half of the US states, the UK, and leading civil law jurisdictions have shifted away from the "reasonable physician standard" towards the adoption of a "reasonable patient standard" and sometimes even embracing a "subjective patient standard."[44,47,52] The latter standards require physicians to provide such information as a reasonable or

the actual patient would need in order to reach a decision about the acceptability of the procedure and its risks and benefits. The contours of reasonable disclosure for experimental procedures have been defined by case law.[53-54] In line with the principles set out in these rulings, patients who have been subjected to medical experiments would need to have been informed about the experimental nature of the procedure, the current status of laboratory and animal testing, the extent and nature of possible criticism from the medical profession, the estimated chances of success, the foreseeable grave risks, the fact that unknown risks could materialize, and the expertise of the medical team in the particular field.[38,43,47]

Where a physician's breach of duty of care towards a patient is established, a possible remaining obstacle to the claimant's action in negligence is causation. If an informed consent action is brought, claimants must prove that the patient would have refused the experimental procedure if adequately informed.[51] However, if patients are in a desperate situation, it may be plausible to assume that they would have nonetheless opted to undergo the procedure even if the additional information had been disclosed.[39] Similarly, if a medical malpractice claim is brought, it could be difficult to show that it was the physicians' actions and not the patient's underlying condition that caused the patient's suffering or death. This would be particularly challenging where the patient had a life-threatening condition, could not be helped by standard therapy, and died as a result of the procedure.[43] Consequently, the tort liability system may not always be an effective means to seek to remedy possible injuries suffered in experimental medical procedures.

Criminal Liability

In addition to risking civil liability, physicians who engage in medical experiments may also face criminal sanctions. Depending on their severity and outcome, invasions of bodily integrity such as those accompanying surgery can technically give rise to criminal liability for assault, homicide and, in some jurisdictions, negligent infliction of injury. Physicians are only protected from criminal liability subject to four cumulative conditions: the surgery is performed for therapeutic reasons, it is reasonable to perform the surgery, the surgery is performed with reasonable care and skill, and the patient has consented.[55]

The assessment as to whether the physician's actions would be in breach of the duty of care closely resembles the approach taken under tort law. For instance, where a medical procedure has been performed without the consent of the patient, under criminal law the physician would be liable for assault or, if the patient died, for involuntary homicide.[56] If the patient has consented, the court will have to determine whether the physician was negligent. Between common law and civil law jurisdictions, there is a difference in approach as to what level of negligence would result in criminal liability. In common law countries, negligence will only give rise to criminal liability if the procedure resulted in the death of the patient and if, in the light of a responsible body of medical opinion, the court finds the negligent conduct to be truly outrageous.[44,57] Under such

circumstances, physicians may be convicted of criminally negligent homicide. In contrast, in civil law jurisdictions, physicians risk conviction for criminally negligent homicide even if their conduct had not been clearly outrageous.[58] Moreover, if the procedure inflicts severe injury but does not result in the death of the patient, the physicians still risk being charged with the crime of negligent infliction of injury.[59]

Disciplinary Proceedings

Physicians who engage in experimental medical procedures may also be subjected to professional sanctions from the regulatory body of the medical profession if they are reported for serious professional misconduct. Disciplinary actions will typically be taken following a civil or criminal conviction but sanctions may also be initiated independently as soon as a breach of the deontological code is alleged. Codes of medical conduct typically contain provisions forbidding engagement in experimental procedures unless laboratory and animal testing has provided sufficient proof of plausibility and feasibility, the benefits are expected to outweigh the risks, and adequate informed consent has been obtained. If the regulatory body finds that these conditions were not satisfied, or if a breach has been demonstrated during civil or criminal proceedings, physicians can be struck off the medical register, temporarily suspended, ordered to refrain from carrying out a certain procedure, reprimanded or warned.[51]

Is Body Transplantation Legally Acceptable Under the Current State of Medical Knowledge?

Prior Ethics Review

In view of these considerations, performing body transplantation under the current state of medical knowledge would undoubtedly raise major legal and ethical concerns. It is inconceivable that an ethics committee would approve a surgical project involving severing the head of a living person and attaching it to the torso of dead person, when serious doubts remain about the feasibility and consequences of the procedure and about the decision-making of participants.

Arguably, body transplantation is one of the most risky surgical interventions imaginable. Consequently, physicians who want to attempt such a procedure would need to inform interested potential recipients that it is highly experimental in nature and that the risks are likely to be immense. More specifically, attention should be paid to the risk of failure of the surgery, resulting in death or loss of sensory, motor and respiratory functions, and to the severe complications and grave unknown risks that may follow a successful surgery. Taking into account these uncertainties, potential recipients may find it very difficult to arrive at a truly informed decision. However, even under these circumstances their consent could still be valid if they have a clear understanding that the chances for improvement look meager and the consequences may well be devastating. In addition, since body transplant experiments will be proposed only as an option of last resort for patients who are facing an imminent and terrible death, the risk-benefit

analysis may still be acceptable in their view. This is evidenced by the reasoning underlying the decision of Valery Spiridonov, suffering from Werdnig-Hoffmann disease, who was the first to step forward as a volunteer for body transplantation.[60]

Although the decision to undergo body transplantation may under specific circumstances be sufficiently informed and well-reasoned, ethics committees will need to ensure that patients who step forward have voluntarily arrived at their decision. In this respect, the desperation of these patients may make them particularly vulnerable to undue influence from physicians who propose the procedure. This risk will increase considerably if the patient depends for his medical care on a physician involved in the procedure or if, as seems to be case in the proposed body transplant by Canavero and Ren, the first recipient will be chosen from a large number of volunteers.[17-19] In order not to compromise their chances, patients who are desperate to undergo body transplantation will be very obliging towards the medical team. As a result, these patients may be very reluctant to raise possible doubts and may even exhibit blind faith in the procedure. With many experts very sceptical about the prospects for success, ethics review should therefore probe whether the selected patients are protected against an excess of zeal on the part of the medical team, whether they are not given false hopes, and, if the procedure is part of a broader research project, whether they would be at risk of a therapeutic misconception.[61]

Although it is conceivable that a patient could validly consent to body transplantation, the prior issue to be addressed by the ethics committee is whether this experimental medical procedure should be attempted. From both a legal and an ethical perspective, approval should only be granted if the risks of body transplantation would be considered reasonable in relation to the expected benefits. However, since major doubts have been raised about the scientific plausibility and clinical feasibility of body transplantation, there is no reasonable expectation that the procedure would currently be successful, let alone that the risks would be acceptable. More specifically, Canavero and Ren fail to provide evidence for their claim that spinal cord re-fusion has been validated in laboratory settings and successfully tested in animals. No ethics committee will be in a position to even consider the application of this procedure to humans before the credibility of this claim has been verified.[62] Moreover, support for the experiment from independent experts seems to be largely absent. In view of this observation, any attempt at body transplantation at this stage fails to conform to legal standards, violates the duty of beneficence, and should be rejected following ethics review.

Even if the ethics committee were to be presented with minimally supportive evidence of the scientific plausibility and clinical feasibility of body transplantation, approval should be refused because the procedure is unacceptably dangerous and the risks cannot be adequately managed. In the absence of convincing proof of the feasibility of spinal cord re-fusion, independent experts have expressed their concern that horrible injuries or even death are to be expected.[5] Consequently, attempting such a procedure would be in clear breach of one of the most basic tenets of the Nuremberg Code. It has

also been acknowledged that the risks involved in body transplantation would require therapeutic strategies that are themselves experimental and unproven. Although Canavero insists that there would be ways to control these risks, adequate risk management cannot be guaranteed before much more scientific research is performed. Consequently, due to the nature, magnitude and likelihood of the risks involved, ethics committees would have no other option but to deny approval of the proposed body transplantation.

Admittedly, it could be argued that body transplantation will first be tried on patients who will face a certain and painful death if they are not allowed to undergo the procedure. The implication that, despite major uncertainties and risks, body transplantation should be allowed because it may carry some benefit for patients who allegedly have nothing more to lose, can be read in some of Canavero's justifications.[63] However, opponents of body transplantation warn that the procedure could leave recipients in a more debilitated state than before, potentially even in a state worse than the death they are trying to avoid.[5] Hence, body transplant recipients may in fact have a lot to lose. Similarly unconvincing is the argument that volunteers should be allowed to sacrifice themselves to further medical science and eventually offer future body transplant recipients better prospects. In line with the fundamental ethical rule set out in, for instance, the UNESCO *Universal Declaration on Bioethics and Human Rights* and the Council of Europe's *Convention on Human Rights and Biomedicine*, the welfare of patients should not be sacrificed on the altar of unbridled medical progress, even if they consent to it. These arguments invalidate Canavero's suggestion that body transplantation should be urgently attempted presuming that, if it could be made to work, it could save desperate individuals who currently have no prospect of a cure. In the absence of convincing proof of the feasibility of the procedure and in view of the likelihood and severity of the risks involved, it is difficult to escape the impression that Canavero's insistence is motivated less by concern for these desperate patients than by his ambition to enter the pantheon of medical heroes.

Moreover, possible societal harms of engaging in body transplantation under the current state of medical knowledge should also be brought into the equation. As evidenced by recent transplant scandals,[64] a premature and horribly failed body transplant experiment would have significant detrimental effects on the public's trust in transplantation and in the medical profession and might well result in a sharp decline in organ donation rates.

In sum, it is clear that none of the conditions required for granting ethics approval for a medical experiment are currently fulfilled with regard to body transplantation. For that reason, it is completely inconceivable that body transplant projects, such as the one proposed by Canavero and Ren, would pass ethics review in countries that have in place clear legal and ethical standards and take scientific and ethics assessment seriously.

Liability and Disciplinary Sanctions

If body transplantation is performed and caused injuries or death, donor body recipients or their next-of-kin may bring a medical negligence claim for damages. If the

medical team carried out the intervention in a civil law country without having solicited an ethics committee or in disregard of a negative assessment, aggrieved parties will even have a direct cause of action for medical negligence. Hence, they will be compensated without having to prove that the medical team committed a medical fault during the intervention. In the inconceivable event that the medical team had obtained prior ethics approval or if they proceeded with body transplantation in a common law country in the absence of ethics approval, aggrieved parties will need to demonstrate that a medical fault was committed which resulted in injury to the recipient.

It can hardly be doubted that physicians who attempt body transplantation under the current state of medical knowledge may well be found liable for medical malpractice. As evidenced by the barrage of criticism levelled at the body transplant model of Canavero and Ren and by the absence of solid public support from experts in the field, it is clear that there is no persistent minority opinion that would currently endorse such a procedure. As a result, evidence presented in support of body transplantation would be closely scrutinized. Even if some experts would be willing to come forward and the patient suffered from a very serious and incurable condition and had consented to the procedure in full awareness of its experimental nature, its meager prospects for success and its high risks, courts would be in no position to disregard the lack of pre-clinical evidential support, the unconvincing medical rationale for body transplantation, and its adverse risk/benefit ratio. Consequently, physicians attempting the procedure will fail to meet the standard of care and would be held liable for medical malpractice.

If recipients or their next-of-kin were to be of the opinion that body transplantation was performed without the information essential to the recipient's decision having been disclosed, they may also bring an action in informed consent. They would need to establish that the medical team had not informed the recipient about everything that, under the standard of care applicable in the jurisdiction concerned, would have been reasonable to disclose. Since body transplantation is a highly experimental procedure, a very high level of disclosure would be required. Considering that experts warn that Canavero and Ren systematically overestimate the chances of success of their proposed surgical protocol, downplay possible risks and inflate their ability to manage them, and dismiss any criticism from their peers, it is readily conceivable that problems in this respect may arise if they go ahead with body transplantation at this stage.

Under the current circumstances medical malpractice and possibly also failure to disclose information required for valid consent would be easy to establish. However, recipients or their next-of-kin may find it more difficult to prove that the injuries sustained during body transplantation were caused by the physicians' breach of their duty of care. Taking into account that in all likelihood the recipient suffered from a life-threatening condition and opted to undergo body transplantation to avoid impending death, it would be a real challenge to prove that disability or death occurring during the procedure was a result of the surgery instead of the recipient's underlying condition. Similarly, if a claim in informed consent is brought, it may be reasonable to assume that

the aggrieved body transplant recipient was so desperate that he or she would still have chosen to proceed even if more extensive and accurate information had been provided. As with other medical experiments, the system of tort liability may not always be an effective means for seeking relief for injuries suffered in body transplantation.

Apart from risking civil liability, physicians engaging in body transplantation will also risk criminal sanctions if they proceed with the procedure under the current state of medical knowledge. In the unlikely event that the recipient had not consented to the body transplantation, physicians would be liable for assault or, if the recipient died, for involuntary homicide. If consent was given, physicians will face criminal sanctions if the court finds that they have acted negligently. In common law countries, criminal liability will only attach if the negligent conduct is considered truly outrageous and resulted in the recipient's death. Although such cases of criminally negligent homicide as a result of unsuccessful medical procedures are very rare, it is conceivable that body transplantation, were it to result in the death of the patient, could be judged as falling so far below the standard of care as to put the physicians involved at real risk of being convicted.

By contrast, if body transplantation would have been performed in a civil law country, physicians would risk criminal prosecution even if their conduct corresponds to a lower level of negligence. They would risk conviction for criminally negligent homicide when the procedure resulted in the recipient's death even though their negligent intervention was not found to be truly outrageous. Similarly, if the recipient was severely injured but did not die as a result of the body transplant, physicians can still be charged if their intervention is considered negligent. In view of the current lack of pre-clinical evidential support for body transplantation, its unconvincing medical rationale, and its expected highly adverse risk/benefit ratio, performing body transplantation would clearly be in breach of the duty of care. Consequently, it can be readily assumed that physicians who in civil law jurisdictions attempt body transplantation that results in the death or severe injury of the patient will be held criminally liable for criminally negligent homicide or, respectively, negligent infliction of injury. If body transplantation had been undertaken in the absence of prior ethics approval, negligent conduct will be presumed and criminal liability will automatically attach.

Finally, physicians who have performed body transplantation risk severe disciplinary sanctions if they have been held civilly or criminally liable or if breach of the deontological code is otherwise proven. Considering that, in body transplantation, significant concerns have been raised with regard to several elements that by the rules of the codes of medical conduct are punishable with disciplinary sanctions—elements such as clear inadequacies regarding the plausibility and feasibility of the procedure, the risk-benefit balance, and the process of informed consent—it is perfectly conceivable that physicians engaging in body transplantation would be sanctioned severely and struck off the medical register.

Conclusion

The proposal by Canavero and Ren to initiate body transplantation has been met with great skepticism from medical experts and ethicists. From a legal and ethical perspective, performing such a procedure under the current state of medical knowledge would raise major concerns. The physicians involved would violate their duties of respect and beneficence towards their patients. Given the lack of evidence that the proposed body transplant model is scientifically plausible, clinically feasible and medically indicated, and taking into account the nature, magnitude, likelihood and difficult management of the risks involved, it seems very unlikely that prior ethics approval would be obtained.

If body transplantation was nevertheless to be performed, physicians are likely to be found liable for medical malpractice because no persistent minority opinion would currently endorse such a procedure. Even if some neurosurgeons and transplant surgeons would be willing to step forward in support, courts are likely to find in favor of aggrieved body transplant recipients or their next-of-kin because of the lack of pre-clinical evidential support for body transplantation, its unconvincing medical rationale, and the adverse risk/benefit ratio.

Similarly, physicians involved in body transplantation that results in the death of the recipient would run a considerable risk of being held criminally liable for criminally negligent homicide. Criminal liability would be particularly likely if body transplantation were to have been performed in a civil law jurisdiction, such as China, even if the recipient was severely injured but did not die as a result of the procedure. The physicians concerned will also risk severe disciplinary sanctions for serious professional misconduct, with a real possibility that they will be suspended or even banned from medical practice for life.

Disclosure

We declare that there is no conflict of interests.

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