

Suspending Informed Consent

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INTRODUCTION

The notion of suspended human animation has long been a topic in science fiction. Whether it is transporting human astronauts to far-off planets or freezing bodily processes for thousands of years, humans have been obsessed. Our biological clocks are constantly ticking and remain a constant reminder of our own mortality. Time is limited, and nowhere is this more evident than in the emergency room. In cases of traumatic injury, the more time the better. This is the current logic at UPMC Presbyterian Hospital in Pittsburgh.

When the human body is at normal temperature, cells require oxygen for metabolic processes to continue normally. However, at lower temperatures, cells require less oxygen, as chemical reactions tend to come to a halt. According to those at UPMC, if one can suspend the bodily processes of a patient while dying, there remains more time to fix structural problems and apply the appropriate treatment prior to death.

ANALYSIS

The process itself involves replacing a patient's blood with cooled saline solution to halt cellular activity. The procedure was originally demonstrated by Alam et al., claiming no deficits in learning and memory.¹ The experimenters induced a hemorrhage in a group of pigs; blood was then drained and replaced with saline or potassium at 10 °C. The animals were then treated, re-perfused, and tested, showing neurologic damage in only three animals.

Doctors at UPMC intend to replicate this procedure to allow for more survival time for the patient. The doctors plan on performing this technique on 10 patients who meet the criteria for this procedure and match this group with 10 additional patients who also meet the criteria, but will not be selected. The research team plans to continue with this procedure until enough patients are treated and there exists enough data to analyze. Notably, the protocol does not require informed consent according to the U.S. Food and Drug Administration because patients will be in a life-threatening condition.²

The lack of informed consent required for participants in this study is suspect due to the limited knowledge of outcomes regarding the procedure. Previous research for this procedure is dependent on the outcome of behavioral memory and learning functions in pigs. Our knowledge of the potential neurological effects of this procedure is not based on any research regarding animals with more human-like intelligence, such as primates.

Moreover, the researchers did find neurological impairment in some of the animals tested, and this was only when testing for learning and memory. The research is unclear on how the procedure may have affected more long-term memories or cognitive functions such as language or facial recognition. Learning and memory may not be affected; however most of this takes place in the hippocampus. This does not preclude the possibility of damage to the frontal lobe, resulting in cognitive defects. The full spectrum of possible risks has not been analyzed; thus, it is imprudent and possibly unethical for researchers to begin research on humans without further data from non-human primates.

CONCLUSION

Furthermore, less than 50 percent of severely or terminally ill patients, in general, have advance directives.^{3,4} It is likely that some of the patients admitted in this study will not have an advance directive. By including patients without advance directives, it is impossible to know how patients will react to involuntarily undergoing this procedure. It is quite possible that a patient will react adversely upon waking to a life where her quality of life has been significantly diminished. What if the patient has to spend his life on a feeding tube? Or perhaps the patient experiences retrograde amnesia? Why do we presuppose an overriding value on the patient's life over their choice? The FDA has sent an obvious message: that autonomy can be violated for those on the cusp of death. At the very least, this story elucidates society's willingness to supersede our ethical principals at the risk of death. The risks of such an operation are unknown and further research is needed before beginning research on humans.

REFERENCES

¹ Alam, H. B., Bowyer, M. W., Koustova, E., Gushchin, V., Anderson, D., Stanton, K., ... & Rhee, P. (2002). Learning and memory is preserved after induced asanguineous hyperkalemic hypothermic arrest in a swine model of traumatic exsanguination. *Surgery*, 132(2), 278-288.

² Code of Federal Regulations, [Title 21, Volume 1] Part 50, Protection of Human Subjects, Subpart B--Informed Consent of Human Subjects Sec. 50.24 Exception from informed consent requirements for emergency research.

³ Teno JM, Licks S, Lynn J, et al. Do advance directives provide instructions that direct care? *J Am Geriatr Soc* 1997;45:508-12.

⁴ Teno J, Lynn J, Wenger N, et al. Advance directives for seriously-ill hospitalized patients: effectiveness with the Patient Self-Determination Act and the SUPPORT intervention. *J Am Geriatr Soc* 1997;45:500-7.

Gunshot victims suspended between life and death:

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End of life preferences:

<http://www.ahrq.gov/research/findings/factsheets/aging/endliferia/index.html>

Exceptions to informed consent:

<http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm249673.pdf>