

Ethical implications of modifying lethal injection protocols

June 10 2008

A team of medical, ethical, and legal scholars argues in this week's *PLoS Medicine* that in some US states the modification of lethal injection protocols is tantamount to experimentation upon prisoners without the prisoners' consent and without any ethical safeguards.

Drs. Leonidas Koniaris and Teresa Zimmers (University of Miami Miller School of Medicine, Miami, Florida, USA) and colleagues lay out evidence obtained in litigation and from Freedom of Information act requests that suggests that at least 10 states are performing regimens that may be akin to human experimentation.

"The collective practice of lethal injection," say the authors, "has employed invasive testing of different drug protocols and devices, data collection and monitoring, and systematic review with outcome data being used to revise practice." Certain lethal injection inquiries, they say, may therefore constitute human subjects research.

While death row inmates have been stripped of the right to freedom and to life, say the authors, they maintain the right to bodily integrity and the right to refuse to be experimented upon. And yet in these 10 states, Koniaris and Zimmer's analysis finds that inmates were not asked for their consent to be included in lethal injection practices, which are essentially experimental in nature.

Guidelines for the ethical conduct of research involving humans, such as the Nuremberg Code and the Declaration of Helsinki, were developed at

least partially as a way of ensuring that medical researchers would not exploit vulnerable prisoner populations. In the US, researchers who conduct studies on humans are required to follow the "Common Rule" (the Federal Policy for the Protection of Human Subjects), which provides protection for research participants by requiring institutional assurance of compliance with federal regulations, institutional review board (IRB) review, approval, and oversight, and informed consent of the participants. In Koniaris and Zimmers' analysis, none of the ten states undertaking regimens with prisoners being executed followed the Common Rule—for example, prisoners had not given consent to be experimented upon and institutional review boards had not approved the use of what is essentially a n experiment protocol.

Lethal injection for execution has largely replaced other execution methods in the US, in part due to the appearance of a peaceful death. But evidence suggests that some inmates suffer extreme pain—triggering legal challenges against lethal injection on the grounds that it violates the United States' constitutional prohibition against cruel and unusual punishment. (see, for example, a previous *PLoS Medicine* paper, by Dr Zimmers and colleagues in 2007: Lethal Injection for Execution: Chemical Asphyxiation? *PLoS Med* 4(4): e156 doi:10.1371/journal.pmed.0040156).

Jurists are now demanding that lethal injection protocols be amended, say Dr Zimmers and colleagues, to comply with this constitutional prohibition. However, even as jurists demand lethal injection protocol changes, say the authors, "corrections officials, governors, and their medical collaborators are left in a legal and ethical quandary—in order to comply with the law and carry out their duties, they are employing the tools and methods of biomedical inquiry without its ethical safeguards."

Given the current guidelines for human experimentation, they say, "it is difficult to conceive of circumstances in which lethal injection research

activities could be carried out in a fashion consistent with these ethical norms, and yet those engaged in such research would seem to be required to do so."

Citation: Citation: Koniaris LG, Goodman KW, Sugarman J, Ozomaro U, Sheldon J, et al. (2008) Ethical implications of modifying lethal injection protocols. PLoS Med 5(6): e126. --
[medicine.plosjournals.org/perl ... journal.pmed.0050126](https://doi.org/10.1371/journal.pmed.0050126)

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Citation: Ethical implications of modifying lethal injection protocols (2008, June 10) retrieved 20 April 2024 from
<https://medicalxpress.com/news/2008-06-ethical-implications-lethal-protocols.html>

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