

Top stories

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Medical experiments to be done without patients' consent

Five-year project aims to improve car crash, cardiac, other treatments

By **ROB STEIN**
Washington Post

WASHINGTON — The federal government is undertaking the most ambitious set of studies ever mounted under a controversial arrangement that allows researchers to conduct some kinds of medical experiments without first getting the patients' permission.

The \$50 million, five-year project, which will involve more than 20,000 patients in 11 sites in the United States and Canada, is designed to improve treatment after car accidents, shootings, cardiac arrest and other emergencies.

The three studies, organizers say, offer an unprecedented opportunity to find better ways to resuscitate people whose hearts suddenly stop, to stabilize patients who go into shock and to minimize damage from head injuries. Because such patients are usually unconscious at a time when every minute counts, it is often impossible to get consent from them or their families, the organizers say.

The project has been endorsed by many trauma experts and some bioethicists, but others question it. The harshest critics say the research violates fundamental ethical principles.

The organizers said the studies are going forward only after an exhaustive scientific and ethical review by the National Institutes of Health, which authorized the funding in 2004, and the Food and Drug Administration, which approved the first phase about a year ago and the second phase six months ago.

The first experiments, involving nearly 6,000 patients, focus on people who are in shock or have suffered head injuries from a car crash, a fall or some other trauma.

About 40,000 such patients show up at hospitals each year, and the standard practice is to give them saline infusions to stabilize their blood pressure. For the study, emergency medical workers are randomly infusing some patients with "hypertonic" solutions containing much higher levels of sodium, with or without a drug called dextran. Animal research and small studies involving people have indicated that hypertonic solutions could save more lives and minimize brain damage.

The next experiment, which will involve about 15,000 patients, is designed to determine how best to revive those whose hearts suddenly stop beating. About 180,000 Americans suffer these sudden cardiac arrests each year.

Emergency medical workers often shock these patients immediately to try to get their hearts

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The studies are being conducted by the Resuscitation Outcomes Consortium, a network that includes medical centers in Seattle, Portland, San Diego, Dallas, Birmingham, Pittsburgh, Milwaukee, Toronto and Ottawa and around Iowa and British Columbia.

started again. But some do a few minutes of cardiopulmonary resuscitation first. Researchers want to determine which strategy works better by randomly trying one or the other — both with and without a special valve attached to devices used to push air into the lungs during CPR. That study is expected to start next month.

"We will never know the best way to treat people unless we do this research. And the only way we can do this research, since the person is unconscious, is without consent," said Myron Weisfeldt of the Johns Hopkins University School of Medicine, who is overseeing the project. "Even if there are family members present, they know their loved one is dying. The ambulance is there. The sirens are going off. You can't possibly imagine gaining a meaningful informed consent from someone under those circumstances."

Before starting the research at each site, researchers complete a "community consultation" process. Local organizers try to notify the public about the study and gauge the reaction through public meetings, telephone surveys, Internet postings and advertisements and through stories in local media. Anyone who objects can get a special bracelet to alert medical workers that they refuse to participate.

The project proceeds only after also being vetted by a set of local independent reviewers known as an institutional review board. Another group of independent advisers known as a data safety monitoring board will periodically review the study for any signs of problems.

Despite such oversight, some previous similar projects have sparked intense debate. Most recently, a study testing a blood substitute called PolyHeme was criticized for putting patients at risk without consent.

In fact, concerns raised by the PolyHeme study and others prompted the FDA to launch a review of the entire program that permits experiments to be done without consent in emergency situations.

"The ethics and policy concern is how you balance the streamlining of research to get the best information to treat patients against the moral imperative to get consent," said Nancy M.P. King, a bioethicist at Wake Forest University School of Medicine. "The emergency consent exception is supposed to carve out a very narrow window. What's been happening is that narrow window seems to be expanding."

Some bioethicists say the new research is more ethical than some of the earlier studies in several ways, including that patients are not being denied highly effective therapies. Most patients who receive the current treatments do not survive.

"I understand why there might be concerns, but I think ethically this is permissible," said Arthur Derse, a bioethicist at the Medical College of Wisconsin, which refused to participate in the PolyHeme study. "The treatments we currently have are unsatisfactory."

But others say that the studies could be done by finding patients or family members who are in a position to provide consent, even though that might make such studies more difficult.

"This just seems like lazy investigators not wanting to try to get informed consent in situations where it is difficult to get it, so they say it is impossible," said George Annas, a Boston University bioethicist. "I don't think we should use people like this."

Annas was particularly disturbed that children as young as 15 might be included in the research.

"Suppose a 15-year-old child is in the back of a car that is in a terrible accident," Annas said. "The EMTs arrive and say: 'We are doing an experiment with two techniques. We think they are about equal. Is it okay if we flip a coin to see how we treat your son? Or would you rather we just give him the treatment we think is best?' Unless you think all parents would have the EMTs flip a coin, consent here is necessary."

Others are concerned patients may be getting experimental therapies that could turn out to be inferior to standard treatments.

"The most promising experimental medical interventions have often been shown to be less effective than standard treatment," said Kenneth Kipnis, a University of Hawaii bioethicist.

The "community consultation" process has also come under fire.

"Community consultation is intended to be a collaboration with the community of potential subjects, not just letting them know what the plan is," said King, the Wake Forest bioethicist.

But Weisfeldt at Johns Hopkins said the critics would be unhappy under any circumstances.

"Some people object to the whole concept of doing any study whatsoever without permission," Weisfeldt said. "We try to explain all the layers of approval we've gone through and that this is the only way we can do the kind of research that could save many more lives in the future."

VOICES OF HOUSTON

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vikinghou wrote:

I can see the logic of this program, but fear this opens a slippery slope that lessens patients' and families' control over health care decisions.

5/27/2007 8:35:26 AM

Recommend (3)

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EdT wrote:

I'm surprised someone hasn't suggested using prisoners for this research. We could shoot them, or induce a heart attack, or use them in place of a crash-test dummy - the conduct the experiments on *them*. If they live - back to the cell. If they don't - tough luck.

~EdT.

5/27/2007 9:25:21 AM

Recommend (6)

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Raven wrote:

Wow, EdT, glad *you're* not on the ethics committee. Would any "prisoner" do? Anyone from someone convicted of petty theft to a non-violent drug offender to a mass murderer?

There is always the risk of a slippery slope, but this seems as ethical as possible, considering that life-saving measures in emergencies are typically done without overt consent and the current measures are not terribly effective. It is not as if they plan to do nothing for some to generate a control group. JMO.

5/27/2007 9:36:50 AM

Recommend (1)

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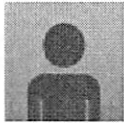
MikeG2 wrote:

Wow!! now you can have a legit reason to despose of a trouble maker, first class murder no repercussions. I feel sorry for the first guy or women that gets that treatment. What is this world coming too.

5/27/2007 11:14:09 AM

Recommend

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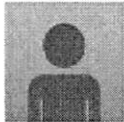
Freethinker4achange wrote:

My son suffered a brain injury in a car accident 10 years ago at age 18. They were experimenting with inducing comas and cooling body temps. to lessen swelling in the brain. With this study, there was time to get our consent. We said yes, knowing there was a 50% chance he would get the trial treatment. He did, and he ended up on disability, but we believe with much milder damage than without the treatment. 10 years later, they use the cooling technique on nearly all brain damaged patients because it works. I was proud that we got to be a part of the advancement in medicine.

5/27/2007 11:20:17 AM

Recommend (4)

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clara_T_Garden wrote:

Ok, so a law abiding citizen such as myself is open to being an experiment without my consent, but yet if this is done to an inmate, its a crime?? Where is the logic here? Inmates cost us approximately \$50,000 per person yearly, these are people who have chosen to live the way they do, it only seems rational to do the experiments on them. After all shouldn't they have to pay for all of the services they have used for their course of conduct? They have already surrendered their constitutional rights to liberty and property by becoming a convict.

5/27/2007 11:50:13 AM

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AngryBaby wrote:

I believe there's a stipulation regarding medical studies using prisoners as subjects that states the study must, among other things, be for a treatment that-if approved-will improve their quality of life/healthcare. This is because of some heinous experiments performed on prisoners in the past.

Prisoners are, believe it or not, treated very carefully because of their classification as an easily exploitable population.

5/27/2007 12:00:55 PM

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Pancho3 wrote:

"I'm surprised someone hasn't suggested using prisoners for this research."

Why use prisoners when you can use soldiers and veterans. We have millions of soldiers and veterans who cannot sue for damages (Ferris Doctrine) and because of years of conditioning (following orders without question) cannot standup for themselves. Furthermore, prisoners have legal advocate groups to protect them (the ACLU), and veterans do not.

Happy Memorial Day!

5/27/2007 12:21:50 PM

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newsaroo wrote:

Wow, forget prison inmates...we've got 12-20 million illegals we can practice on. We can shoot them at the border, crash the cars of coyotes etc. They want free health care don't they?

5/27/2007 12:22:15 PM

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