



# Premature Babies Study Raises Debate Over Risks and Ethical Consent

By Sabrina Tavernise

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Two years ago, researchers in a clinical trial involving oxygen levels for the tiniest premature babies were accused by a federal watchdog agency of not properly disclosing the risks to families who participated.

What followed was extensive public scrutiny of the trial, called Support, and soul-searching in the research community about how best to obtain informed consent from participants. Some families sued, arguing that their babies suffered serious injuries as a result of their treatment.

But last month, a federal judge threw out the suit, saying the families could not prove that the trial caused the injuries. Last week, the editors of a prestigious medical journal wrote that the decision showed that the trial was solid to begin with.

“What the judge was saying was that being in the trial didn’t cause the bad outcomes for these kids,” said Dr. Jeffrey M. Drazen, editor in chief of The New England Journal of Medicine and an author of one of two pieces supporting the study. “And if that’s the case, there’s nothing to complain about in the consent form.”

But some bioethicists disagreed.

“The consensus in the bioethics community was that the informed

consent was not adequate, and that hasn't changed," said George J. Annas, director of the Center for Health Law, Ethics and Human Rights at Boston University's School of Public Health.

The lungs of babies born prematurely are typically underdeveloped, and they often need to be given oxygen. But too much and too little are both bad, so researchers were conducting the study to find the sweet spot, trying certain concentrations on babies born months premature, at just 24 to 27 weeks of gestation.

But in 2013, the Office for Human Research Protections, the federal office that safeguards people who take part in government-financed research, sent a letter to the University of Alabama at Birmingham, the lead site in the study, stating that researchers had failed to warn the families that enrolling a baby in the study could increase the chances of blindness, if the baby was among those given higher concentrations of oxygen, or death, if the baby was among those given less.

Researchers defended their actions, saying that all of the approximately 1,300 babies in the study had been kept within a band of treatment that was the standard of medical care at the time — oxygen saturation levels of 85 to 95 percent. They argued that doctors did not know which part of the spectrum was better and that until the trial, which was created to try to answer that question, they had really only been guessing.

Ultimately, mortality was fairly high in the low-oxygen group: 130 babies out of 654 in the low-oxygen group died. Ninety-one babies out of 509 in the high-oxygen group developed an eye ailment. Researchers disputed the assertion that the babies were worse off for having been in the study; born so early, they said, these children were at high risk to begin with.

On Aug. 13, Judge Karon O. Bowdre of Federal District Court for the Northern District of Alabama seemed to accept that view. She threw out

the lawsuit by the families, reasoning that they had not shown that the Support trial caused their babies' injuries. The trial may have increased their risks, the judge wrote, but that was not enough to hear the case.



Dr. George Annas, a bioethicist at Boston University, said that informed consent was not obtained in a study of oxygen levels for premature babies.

Shiho Fukada for The New York Times

"As the old axiom goes, correlation does not equal causation," Judge Bowdre wrote. She said the babies' extreme prematurity "already put them at a very high risk." The fact that the babies' injuries "are consistent with" oxygen levels that could have inflicted them "does not show" that those levels caused them.

Critical questions about the case were left unanswered — for example, whether the researchers knew ahead of time that the risk of death increased at lower oxygen levels. (Dr. Drazen insists they did not, but critics, including the federal watchdog, say researchers knew it was a

concern but did not spell it out to families.) HEALTH | Premature Babies Study Raises Debate Over ...

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Even so, the medical community rejoiced. One opinion piece in The New England Journal of Medicine trumpeted: “Vindication for Support.”

Professor Annas said the ruling simply meant that the families could not prove the study had caused the injuries, but that did not mean that it had not or that the consent forms, which he argues played a small role in the case, were obtained properly.

A good analogy, he said, was the decision by a federal judge last week to throw out a four-game suspension of the New England Patriots quarterback Tom Brady over his role in the deflation of footballs.

“That decision does not mean Brady is innocent any more than the Bowdre decision means that informed consent was properly obtained,” he said.

But others said the lawsuit’s failure was important, because it tipped the scales in favor of the researchers.

“This decision will mean, from a policy and practical point of view, that this kind of research is going to move on,” said Arthur Caplan, head of the division of medical ethics at NYU Langone Medical Center. He said if the judge had agreed to hear the case, “we’d have research slowing down, everyone waiting to see the outcome of a trial before starting projects.”

As for the New England Journal of Medicine authors, “they are a little enthusiastic,” he said, “but they are mainly right because they are breathing a giant sigh of relief that the legal system didn’t find enough to call the Support study researchers to task.”

Even so, the issue remains unresolved. The federal government is trying to come up with more explicit guidance about the consent process. A

final version is expected next year. And the office that first found the trial's consent practices lacking stands by its conclusion.

"The consent form was inadequate at the time of the study, and the court ruling doesn't change that," said Dr. Jerry Menikoff, director of the Office for Human Research Protections.

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