# English hospital censured for using premature babies as human "guinea pigs"

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**13 May 2000**

North Staffordshire Hospital, Stoke on Trent, has been censured for allowing doctors to conduct clinical research on babies without obtaining parental consent.

It is the outcome of a 15-month inquiry into trials of a ventilator to aid breathing, in which 28 premature babies died and 15 were left brain damaged. The inquiry report has called for tighter controls to ensure patients are not used as “guinea pigs” in clinical tests. Allegations of forged consent forms have been passed to the General Medical Council.

The investigation was carried out by Professor Rod Griffiths, director of West Midlands public health, and focused on the way the clinical trials performed by consultant paediatrician Professor David Southall were conducted. Southall and another consultant at the hospital, Martin Samuels, were suspended last December. It is not the first time that Southall has courted controversy. He was previously criticised for his use of covert video surveillance of mothers suspected of having harmed their babies. Thirty-three parents or stepparents were prosecuted as a result.

The report indicts the existing system within the National Health Service (NHS) for allowing adults and children to be used in experiments. Governance systems employed at North Staffordshire Hospital at the time of the ventilator trials were broadly in line with Department of Health guidelines. The section of the report dealing with “Roles and Responsibility in Monitoring” also makes clear that finance was a key factor in the short cuts used by Professor Southall. The Review Panel was told that to have designed and managed a better trial would have cost more money. The project went ahead anyway, which meant that full discussion of the trial did not take place.

Between 1989 and 1993 the experimental ventilators were used on 122 premature babies. Premature babies develop breathing problems because their lungs do not make enough surfactant, a wetting agent, which creates the correct surface tension for the lungs to function. Without it, the insides of the lungs tend to stick together, making it harder to take in oxygen.

The method used to assist premature babies breathing was called Continuous Negative Extrathoracic Pressure (CNEP), which involves placing the child in a slightly depressurised incubator. This works on the same principle as an iron lung, which was used in the 1930s, 40s, and 50s to treat babies with polio who had difficulty breathing. This “lung” creates a greater pressure inside the chest than outside.

A baby is placed inside a clear acrylic box, resembling an incubator, which creates an airtight seal around its chest. Air can be sucked out of the container, creating a vacuum, while the baby's head remains outside the ventilator. The greater pressure inside the baby's chest means that the lungs will inflate, enabling the baby to breathe. This contrasts with the conventional method, which uses “positive pressure” by inserting a tube into the throat to pump air into the lungs. This way pressure can be measured and adjusted.

Debbie and Carl Henshall, who had two of their babies experimented on in 1992, were the prime movers behind the inquiry being called. Their daughter Stacey died on a ventilator at the hospital in February 1992 and her sister Sophie, born in November 1992, suffered brain damage and is permanently disabled.

Mrs. Henshall was told that the treatment was newer and safer, not experimental. Express consent for her child to take part in the trial was never sought. Mrs Henshall told *BBC News*, “I didn't find out until my second daughter, who had received the treatment, was four years old that the treatment was part of a trial and the equipment was experimental. I find that incredible.

I just can't believe they can do that. I know my way around a prem unit, having had six premature babies, but basically they fooled me.”

Mr. Henshall explained that he and his wife had not given their consent for the treatment and that the form stating the opposite was a forgery. “The consent form has Sophie's name on it, which is impossible because Deb and I didn't decide until the next day we were going to call her Sophie,” he said.

Sharon Bradley's son Stephen is now seven years old. He has autistic features and severe learning difficulties. He cannot talk and attends a special school. Sharon said, “There was nothing on the form to suggest it was a trial in any way. I made sure I read all the wording. If I knew what I was really signing, then I wouldn't have given my consent. No sane parent would allow their baby to go through an experiment at that critical stage.”

Mrs. Henshall said the inquiry report was a “step forward”, but felt that it still left unanswered questions. The Henshall's have restarted legal proceedings against the hospital in pursuit of damages for Sophie.

The most important recommendations of the report are that formal guidance on research governance should be developed and issued to both the NHS and to partners whose research it hosts. It calls on the Department of Health (DoH) to produce guidelines to clarify procedures.

It also highlighted the fact that the trial did not follow up the children to see whether brain damage showed up after they went home. There was nothing in the rules to safeguard parents and children taking part in the trials. The report points out that Southall was "the senior academic in the responsible group. As far as we can tell he took relatively few steps to make sure that the project was in fact run in accordance with the research application." Most of the work was supervised from a distance.

Commenting on the report, Dr. Michael Wilks, chairman of the British Medical Association's medical ethics committee, said, "The days when patients simply left it to doctors to try what they thought best are over. But obtaining informed consent is always complex and can be a very difficult matter, particularly in an emergency or when patients are ill or distressed.... That makes it all the more important that doctors are clear about their ethical obligations and that hospitals have robust procedures for obtaining consent and for approving research."

Professor Southall's other work was also looked at, including a hypoxia trial that exposed healthy babies—whose parents had volunteered them to take part—to low oxygen levels. This was to test a hypothesis that flying in an aircraft with reduced oxygen could be a factor in subsequent cot death. The report states, "In fact the trial could not have investigated this because the type of hypoxia created was not that which is experienced in the reduced partial pressure found in aircraft cabins."