

Hospital criticised for not obtaining proper consent

Adam Legge *Bristol*

Tighter controls on clinical research in the NHS are to be introduced by the government in response to a highly critical review of a study carried out at North Staffordshire Hospital NHS Trust.

The review has raised serious concerns over the issue of consent for a trial on neonates with respiratory failure run by Professor David Southall, consultant paediatrician at the hospital. The randomised controlled trial looked at the effect of treating premature babies with continuous negative extrathoracic pressure (CNEP) ventilation instead of standard ventilation.

The results showed improved respiratory outcomes with the new method but an increase (which was not statistically significant) in baby deaths (*Pediatrics* 1996;98:1154-60).

The review's author is Professor Rod Griffiths, director of public health at the West Midlands regional office of the NHS Executive. He concluded: "What was totally unacceptable to [par-

ents] was the apparent lack of adequate explanation, of choice and consequent properly elicited and recorded consent, and of involvement in later decision making."

The review was set up after Carl and Debbie Henshall, whose two daughters received CNEP ventilation, took their complaints to their local MP. Their first baby, Stacey, died while on a ventilator in February 1992, and they allege that a "trainee midwife" asked if they would like her to receive "a kinder and gentler treatment" rather than having a tube inserted into her throat, while at no point explaining that it was an experimental treatment.

Their second daughter, Sofie, was admitted to the neonatal intensive care unit 10 months later and received CNEP ventilation, although the Henshalls say that they did not sign a consent form.

The review says that Professor Southall "seems to have assumed that the obtaining of consent was



Professor Rod Griffiths: lack of explanation to parents was "totally unacceptable"

proceeding as intended but does not appear to have ensured that each member staff who might be involved in the project was trained or supervised."

Although Professor Southall was responsible to a "significant extent" for the design of the study, the local research ethics committee comes in for criticism. They failed to examine the

study closely enough to see that supervision and management failures "were virtually built into the design." □

Report of the Review into the Research Framework in North Staffordshire is available at www.doh.gov.uk/wmro/northstaffs.htm.

Full story in News Extra at bmj.com

Mbeki appoints team to look at cause of AIDS

Pat Sidley *Johannesburg*

The South African president, Thabo Mbeki, last weekend hosted a meeting of more than 30 scientists for a two day discussion on HIV and AIDS—particularly on the aetiology of AIDS.

At least half of the Presidential Advisory Panel on AIDS, as the group is now known, are scientists and doctors who have disputed the orthodox views on AIDS. Many of these do not believe HIV causes AIDS.

The establishment of the panel has caused intense debate, and, together with President Mbeki's generally unorthodox approach to the looming AIDS catastrophe in South Africa, has caused concern in foreign governments, most notably the United States.

At the end of the two day session a four person team was appointed (two "orthodox" scientists and two dissenting ones); this team will review scientific data and construct experiments to deal with questions that may as yet be unanswered.

The team consists of Professor Malegapuru Makgoba, who is the president of South Africa's Medical Research Council and who aggressively supports the

accepted scientific views on AIDS; Dr Helene Gayle of the Centers for Disease Control and Prevention in Atlanta, whose opinions are similar to those of Professor Makgoba; and Dr Peter Duesburg and Professor Harvey Bialy, both of whom believe no proof exists that HIV causes AIDS.

The team and panel will work in a closed internet session for the next six to eight weeks and will then convene again in South Africa with suggestions for policy for President Mbeki.

The meeting last weekend took place against the background of a letter written by President Mbeki to President Bill Clinton, Prime Minister Tony Blair, and several other

world leaders, expressing his views on HIV and AIDS.

The letter, which was leaked to the *Washington Post*, drew immediate fire from most commentators, as well as from the US administration. In the letter President Mbeki once again expressed his doubts that HIV causes AIDS.

Both in the letter and at the launch of the meeting, President Mbeki construed the reaction to his views as similar to the tyranny experienced by the oppressed in South Africa during the apartheid era. "In an earlier period in human history, these [dissidents] would be heretics that would be burnt at the stake!" he said in the letter. □