



Mr Godo



Dr Koech



Dr Nyikal



Dr Muga



Dr Meme



Sr Owens

Govt probes Aids experiments

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he conceded that he had not met scientific protocols which include getting ethical clearance from the National Council for Science and Technology and being affiliated to a local institute licensed to undertake research.

Medical reports published overseas confirm exports of blood samples from Nyumbani to some European research institutes. Fr Angelo D'Agostino, the Catholic priest who runs the institution, couldn't be reached for comment as he was said to be out of the country. He will return in the first week of June.

But the chief manager at Nyumbani, who said he was in charge in the absence of Fr D'Agostino, Mr Protus Lumiti, acknowledged that Dr Miller from Cambridge University visited Nyumbani last month with his friends to explore the possibility of working with the home on a research on food supplements.

Once the home received his proposal in April, Mr Lumiti said, they handed it over to the authorities for action. He was aware that Dr Miller visited other institutions, including the University of Nairobi and the Kenya Medical Research Institute and talked to their scientists with a view to selling his idea to them.

Saying that it was the second time Dr Miller was visiting the home, Mr Lumiti denied that any blood or other samples were taken from the children and exported to Cambridge.

"If, indeed, any samples were taken from the children, I am with the children 24 hours a day. No blood or any other samples taken from the children were exported," said Mr Lumiti.

He said that although the Government had recognised the home as the legal custodian of the children, no research would be undertaken there without its consent.

Mr Lumiti laughed it off when he was informed that the home was being investigated for allowing research on HIV/Aids without consent from the

relevant government authorities. He said those allegations had been raised all along since the home was set up 10 years ago.

A member of the Nyumbani Board of Directors, Sister Mary Owens, said she was not qualified to comment on the status of scientific research undertaken at the home.

She said: "I am not aware of any unauthorised studies at the home as I am not a medical doctor and, therefore, would not know if the children are being used as guinea pigs. I am only a counsellor."

Nyumbani Children's Home, which caters for orphans whose parents have died from HIV/Aids, is not authorised to undertake the kind of research Dr Miller was conducting. It would seem Dr Miller, who was accompanied by a colleague, was acting on the assumption that since scientists led by Dr Sarah Rowland-Jones of the University of Oxford's Nuffield Department of Medicine had not only taken blood and other samples from the children but also exported the materials to Britain without the authority or ethical clearance from the government, he too could do the same.

The orphanage, which is officially registered as a limited company under Cap 486 of the Companies Act, is home to 70 children but indirectly caters for about 1,000 others through community projects in the city's slum areas. It raises funds from the United States Agency for International Development (US-Aid), among other international aid agencies.

Earlier investigation

The Permanent Secretary for Health, Mr Wellington Godo, told the *Sunday Nation* last week that he had instructed the Director of Medical Services, Dr James Nyikal, and the Director of the Kenya Medical Research Institute, Dr Davy Koech, to follow up on an earlier investigation into the controversial Aids research, which was ordered by a former

Minister for Health, Prof Sam Ongeru.

The earlier investigation came about after a senior research scientist and head of virology at the Institute of Primate Research, Dr Moses Otsyula, who had set up a diagnostic laboratory at the orphanage on behalf of the institute for continuous monitoring of the infected children, blew the whistle on the clandestine study that he discovered was being carried out in April 2001 by Dr Rowland-Jones and her students, Rana Chakraborty and Jedidah Dixon.

Dr Otsyula's complaint was based on the grounds that the University of Oxford researchers had taken blood samples from the children without the permission of either the Government or the home's board of directors, a position the then chairman of the home, long-serving diplomat Dennis Afande, had confirmed.

Also being questioned was a decision by Fr D'Agostino to allow the British researchers to export to the UK both fresh blood samples and frozen ones.

The researchers from the University of Oxford, despite conceding that the protests from Dr Otsyula were valid and

investigation team headed by Dr Koech was set up, but its work was disrupted by the 2002 General Election that saw Kanu lose power to the National Rainbow Coalition.

Dr Muga, before he was replaced late last year, had sought additional information about the research. The documentary evidence presented to the ministry in September last year, and which was made available to the *Sunday Nation*, indicates that besides the illegal research at the orphanage, and export of the blood samples, the Oxford researchers had published two articles.

The first paper was published in the *Annals of Tropical Paediatrics* (2002) 22: 125-131 and is titled *The Post-mortem Pathology of HIV-1 Infected African Children*. It is authored by Rana Chakraborty, Angelo D'Agostino and others. Fr D'Agostino is not a scientist.

No consent given

But that is not where the inconsistencies end. On page 127, the report indicated that consent to publish the findings was obtained from Internal Ethical Review

The report shows that samples used to reach the conclusions were obtained from Nyumbani

that they had breached scientific protocol since no permission was sought from the Ministry of Health or ethical clearance obtained from the Government, went ahead to publish their report in scientific journals and to present papers at international meetings.

The *Sunday Nation* has established that Prof Ongeru, then Permanent Secretary Prof Julius Meme, and a former Director of Medical Services, Dr Richard Muga, were informed about the goings-on at the orphanage and an

Board of the orphanage. This board, the *Sunday Nation* has been reliably informed, has no mandate to give such consent as it is not affiliated to the Health Sciences Specialist Committee of the National Council for Science and Technology.

The second research was published on March 26, 2003 in the *Clinical Infections Disease Journal* pages 36: 922-924. The article was titled *Viral Co-infections Among African Children Infected with Human Immunodeficiency Virus Type 1*.

The authors are given as Rana

Chakraborty, Gereth Rees, Dimitra Bourboulia, Jedidah Dhon, Alexandra M. Cross and Angelo D'Agostino.

The report indicates that the samples used to reach the conclusions in the research were obtained from Nyumbani Children's Home. The article also indicates that informed consent was obtained from the legal guardian of the children. It is also indicated that the Research Ethics Committees at the University of Oxford and the National Council of Science and Technology in Nairobi approved all the studies.

But the only ethical clearance granted in connection with tests at Nyumbani was to Dr Otsyula, through the Institute of Primate Research, on January 8, 2001. It is, however, not transferrable as a researcher has to submit a proposal which is reviewed before the go-ahead is granted.

Kenyan researchers say that lack of ethical clearance and the questionable export of blood samples have undermined the credibility of the study.

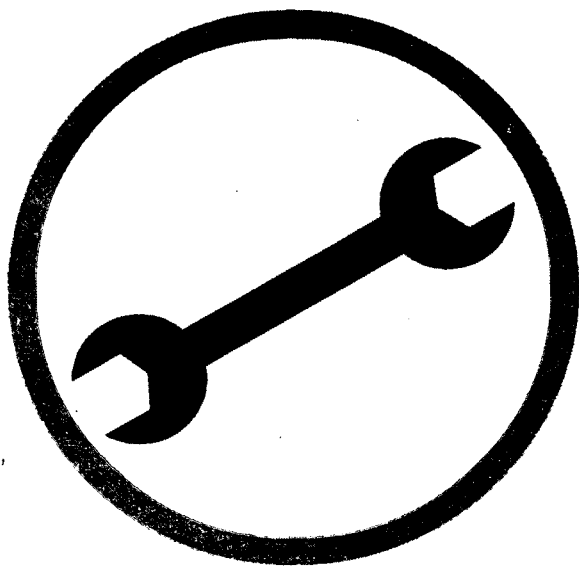
Export of blood samples

Fr D'Agostino is on record as having denied allowing any research at the home, despite publication of the two articles. However, he has sought to justify the export of the blood samples on the grounds that Kenya does not have the laboratory facilities required to undertake the kind of study done at the University of Oxford.

In the March 26, 2003 article, the authors assert that they received informed consent from the children's guardian, but the guardian of the children is not Fr D'Agostino; it is the orphanage's board of directors. It is understood that the board turned down the request from the researchers.

Besides, the *Sunday Nation* has learnt that, even if the cleric was qualified to be the children's legal guardian, it would be unethical for him to carry out research on them.

Reported by David Okwembah, Victor Bwire and Patrick Nzioka



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