

NEWS

Controversy surrounds proposed xenotransplant trial

Amidst much controversy, the Cook Islands government is expected to confirm this week that it will allow a small safety study of transplantation of encapsulated pig pancreatic islet cells into patients with type 1 diabetes. Plans to do the trial in neighbouring New Zealand have already been rejected by that country's government on safety grounds. The International Xenotransplantation Association (IXA) has also raised concerns about the research.

In July last year, the New Zealand Ministry of Health rejected an application from Diatranz, an Auckland-based drug company, to do a trial in New Zealand, mainly on grounds of concerns about the risk of transfer of porcine endogenous retroviruses (PERV). A Ministry statement at the time noted that this was the fourth time an application had been lodged by Diatranz: "The first application was approved because it was before information about [PERV] to humans was published. The second application was withdrawn after this information was published and the most recent two applications have been declined because of concern about retroviruses."

Diatranz subsequently applied to do the research in the Cook Islands in the South Pacific. The Cook Islands is an internally self-governing island state in free association with New Zealand. The nation of 20 000 people has one of the world's highest rates of diabetes. Cook Islanders are New Zealand citizens and can travel to New Zealand to receive health care. The New Zealand Ministry of Health wrote to the Cook Islands government to express its concern and has provided a copy of its decision that was given to Diatranz.

Bob Elliott, the medical director of Diatranz, rejected the New Zealand ministry's concerns, saying that any risk of retroviral infection was "miniscule" and that similar transplantations had taken place

"hundreds of times without infection". Elliott said that Diatranz would do the research as though it was taking place in the USA, in accordance with Food and Drug Administration (FDA) guidelines.

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Risk of PERV transfer remains a concern

However, Bob Boyd, the New Zealand Ministry of Health's chief adviser on safety and regulation, said that it was not possible for Diatranz to comply with the international guidelines, which are based on those of the FDA, because this guidance states that researchers should not do trials in a country with a lesser regulatory framework than the researchers' domicile country. Boyd said the Ministry was particularly concerned about issues of informed consent and monitoring, and noted that "the actual implantation of the cells is a minor part of a long safety process involving lifelong monitoring of the patients and their family members".

Diatranz made a series of presentations in the Cook Islands last week. The country's Prime Minister, Robert Woonton, backs the company's plans, saying that he can see no compelling evidence that the trial should not go ahead. However, the country's Chamber of Commerce says it is not satisfied with the company's plan and believes that the Cook Islands does not have the infrastructure to provide the oversight and monitoring such a trial would need.

Elliott said that no financial inducements had been offered at this

stage, but that the Cook Islands government may benefit at a later stage from successful drug development.

Commenting to *The Lancet*, the past-president of the IXA, David K C Cooper (Massachusetts General Hospital, Boston, MA, USA), said: "We would frown on this considerably—they're trying to do a trial outside the regulatory system, and there is a small risk involved in it."

On behalf of the IXA, Cooper and two colleagues sent a letter to the New Zealand Minister of Health, which is to be published in *Transplantation* and *Xenotransplantation*. The letter notes that, at the IXA congress last year, a presentation was made on the treatment of diabetic children in Mexico City with encapsulated pig islets that had been prepared in New Zealand and transported to Mexico for the trial. "This trial raised concern in the minds of many members of the IXA", the letter states, because of the lack of regulation of xenotransplantation in Mexico, and because "the trial was carried out in children, and the extent of informed consent remains uncertain". The letter goes on to state that "organisers of transplantation meetings and the editors of journals should insist that, as a condition of acceptance of a paper for presentation or publication, clinical trials of xenotransplantation should have been carried out under internationally accepted guidelines".

Elliott, however, described the correspondence as a "poison pen letter" and rejected suggestions that Diatranz was exploiting a poor country, describing the Cook Islands as "like a resort, with good health care facilities" and saying it was unfair to describe it as a third world country. Elliott said that all samples would be sent to New Zealand and that his company would provide the medical staff. The trials will be monitored by an independent company that has yet to be appointed, Elliott said.

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