



New Zealand Nurses Organisation Submission to the National Health Council

on the

CONSULTATION DOCUMENT ON APPLICATION OF LIVING CELL TECHNOLOGIES TO CONDUCT A TRIAL OF PIG CELL TRANSPLANTATION IN 8 PATIENTS WITH TYPE 1 DIABETES

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EXECUTIVE SUMMARY

1. The New Zealand Nurses Organisation (NZNO) thanks National Health Council and the Ministry of Health for the opportunity to comment on Living Cells Technologies' (LCT) application to conduct a pig cell transplant trial on eight patients.
2. NZNO notes that there is a certain amount of risk in cutting edge biotechnologies; that some aspects of LTC's research have aroused concern; and that the same research is not conducted in similar OECD countries.
3. NZNO is also aware that diabetes is a chronic disease reaching epidemic proportions in Aotearoa and elsewhere; that porcine islet transplantation is a promising avenue of research for treating this widespread chronic disease; and that excellence in biotechnologies is a key strategic and economic platform for New Zealand.
4. NZNO believes that New Zealand has been proactive in engaging the public, policy makers and scientists in examining the issues around genetic biotechnologies in a transparent and considered way. We have confidence in the regulatory framework, and the expertise and integrity of those responsible for ensuring that studies are well designed to minimise risk, and that they are conducted ethically.
5. We trust that the potential of a highly significant breakthrough in the treatment of a chronic disease and potential risks will be balanced carefully and note that results will be subject to intense international scrutiny.
6. NZNO agrees that the trial application meets the five criteria.
7. NZNO draws your attention to the strong and special interest that nurses have in potential therapies for diabetes and suggest that every effort is made to keep them well informed because of the primary role they play in the long term care of diabetic patients.

8. NZNO also draws your attention to the submission made by the Diabetes Nurse Specialist Section of NZNO.

ABOUT THE NEW ZEALAND NURSES ORGANISATION

9. The New Zealand Nurses Organisation (NZNO) is a Te Tiriti o Waitangi based organisation which represents over 41 000 nurses and health workers. NZNO is the professional body of nurses and the leading nursing union in Aotearoa New Zealand. Our members include nurses, midwives, students, health care workers and other health professionals.
10. The NZNO vision is “Freed to care, Proud to nurse”. Our members enhance the health and wellbeing of all people of Aotearoa New Zealand through ethically based partnerships. Our members are united in the achievement of their professional and industrial aspirations.
11. NZNO has consulted members of the Research and Diabetic Nurses, NZNO staff including Management, Professional Nursing Advisors, Policy Analyst, Industrial Advisors and, in particular, our Researcher Dr Leonie Walker who has considerable clinical and research experience in the field of diabetes.
12. We have also consulted Dr James Shaw, an internationally renowned transplant diabetologist at the Diabetes Research Group at the Institute of Cell and Molecular Biosciences, Newcastle on Tyne.

DISCUSSION

13. NZNO notes that this research, and particularly the rapidity with which it is being brought to human trial stage because the risk of zoonosis related to porcine endogenous retroviral infection has excited some national and international criticism. It is not clear whether the isolation of the pig population per se will give enough protection against possible zoonoses.
14. NZNO notes that not all scientists are convinced that using this particular pig population and encapsulating the pancreatic cells in seaweed gel are sufficiently robust precautions against xenograft mediated hyperacute

rejection. Other teams are exploring the use of transgenic animals whose cells have been genetically modified human HLA molecules.

15. Though diabetes is a chronic disease which increases the risk of many others, it is amenable to treatment. Type I diabetes usually manifests at a young age, so if rejection is a factor, it is possible that insulin dependence will merely be replaced with a similar lifelong dependence on immunosuppressant drugs, with their attendant problems. For women there is the added risk of pregnancy and the unknown effects on the foetus.
16. There is, however, a strong feeling internationally that porcine islet transplants should be pursued (within the right regulatory framework and in optimally designed studies) given their similar physiology to humans, unlimited availability and the potential for transgenic pigs / genetic manipulation.
17. NZNO believes that New Zealand has both the framework and the necessary expertise to consider pursuing this research and that it is infinitely preferable that it is conducted in this environment, where there is an established culture of transparency and caution.
18. Nursing is an evidence-based profession and as such NZNO supports properly conducted clinical trials and scientific investigation.
19. Nursing is also grounded in the “hands-on” delivery of expert care which is complementary to, but qualitatively different from, the healthcare perspective of medical and research experts. It is nurses who are primarily responsible for the day-to-day management of chronic diseases such as diabetes, from education and instruction to careful monitoring, observation and appropriate referral.
20. Nurses also witness first-hand the effect that diabetes has on patients and their families over time. A nurse is likely to be the first clinician that patients discuss a chronic condition, or alternative therapies, with; s/he will almost certainly be the first to notice any change. It is therefore of the utmost

importance that nurses are kept well informed about current research, and are able to answer questions accurately and confidently.

21. Should this trial proceed, NZNO urges that appropriate information and resources be given to nurses and the public, to meet the widespread interest it will certainly generate. Nurses should not be left to face the demands and questions of patients anxious to access new therapies without adequate training and resources.
22. Nurses are acutely aware of the human and financial cost of diabetes. The alarming rate at which it is increasing makes it unlikely that New Zealand will be able to meet growing demands for diabetic-related health care such as dialysis and kidney transplants. In that context, an alternative treatment which may relieve suffering and reduce costs would be very welcome. We note that the Diabetic Nurses Section is of the view that “the expected benefits to patients with type1 diabetes is deemed to significantly exceed any potential risk/s”.
23. NZNO acknowledges the high level of expertise in our hospitals, universities, Crown Research Institutes and Centres of Excellence and believes that cutting edge research is essential to maintain that excellence. We note that biotechnologies was identified as a key driver of innovation in the Growth and Innovation Framework and agree that there is potential for significant health and economic benefits in this direction.
24. NZNO notes that xenotransplantation is not acceptable to some cultures, including Maori, and that that position is respected.
25. Similarly NZNO believes the ethical and spiritual positions of both individuals and religious and spiritual groups have been considered and are respected.
26. NZNO notes that the subjects have all volunteered for the trial, that there are processes for ensuring that are properly informed and that, in the event of mishap, they will be cared for.

CRITERIA

27. While it is understood that the LCT is unable to rule out absolutely the likelihood of transmission of Porcine Endogenous Retrovirus (PERV) and/or other zoonotic diseases, we endorse the opinion of the expert advisory committee (GTAC) that the trial does not pose an unacceptable risk to the health and safety of the public.
28. NZNO notes that the government is taking responsibility for the risks to the trial patients and assumes that a management plan for contingencies is a necessary part of the application and has been approved.
29. We believe the Ethics Committee is an appropriate body to address Ethical, Cultural and Spiritual issues and endorse their decision.
30. NZNO agrees that the trial meets the five criteria.

CONCLUSION:

In conclusion, the New Zealand Nurses Organisation again thanks you for the opportunity to comment (thought the timeframe was extremely short!) and recommends that you:

- **note** our agreement that the trial meets the five criteria;
- **note** our confidence in the regulatory framework and expertise of relevant bodies such as the Gene Technology Advisory Committee and the Bioethics Council to make decisions and recommendations acceptable to most New Zealanders; and
- **agree** that nurses, particularly those involved in the primary care of diabetic patients, should be kept well informed about all aspects of this research.

Marilyn Head
NZ Nurses Organisation

Appendix 1

Diabetes Nurse Specialist Section, NZNO Submission

Submission Re Xenotransplantation Trials

Based on the limited information available from the National Health Committee, the proposed phase I/IIa trial investigating the safety of inserting non-genetically modified pig pancreatic cells encapsulated in a sea-weed based gel into the abdomens of 8 people with type 1 DM promises ground breaking treatment option and hope of the many thousands of individuals inflicted with the disease. Certainly the pre-clinical trial non-human studies indicate that the procedure is associated with significant expectation of benefit.

In reply to the question asked by the NHC “do you think the proposed trial meets the 5 criteria” as set out under section 96E(1) of the Medicines Act 1981, the DNSS, while not experts in the field of xenotransplant, respond as follows:

- 1. Conduct or class of procedure does not pose an unacceptable risk to the health or safety of the public.** While it is understood that the LCT is unable to rule out absolutely the likelihood of transmission of Porcine Endogenous Retrovirus (PERV), it is of our view that the expected benefits to patients with type 1 diabetes is deemed to significantly exceed any potential risk/s.
- 2. Any risks posed by the conduct/class of procedure will be appropriately managed.** While the available information did not stipulate LCT’s intended management plan of risks if they occur, it is assumed that such contingency plans would be in place and that the Gene Technology Advisory Committee (GTAC) would have revised this in conjunction with the scientific assessment which it has condoned.
- 3. Ethical issues.** Yes, adequately addressed
- 4. Cultural issues.** Presumably this was addressed along with the ethics application – not stipulated in information to hand.
- 5. Spiritual issues.** Again, not stipulated in information available, however would imagine that this was taken into consideration with ethics application.

Based on available information to date the DNSS believes that the LCT meets the 5 criteria required by the NHC in its application and support the progression of this phase I/IIa trial.

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