

Genetic research: some ethical issues

LOANE SKENE

LLM, LLB (Hons)

Series Editor

PAUL NISSELLE

MB BS, FRACGP

A research project being conducted in Tonga by an Australian biotech company (Autogen) has been the focus of recent press coverage. We take a look at some of the ethical issues raised.



It is therefore vital that the research be conducted with the appropriate safeguards in place and in compliance with certain ethical standards for research.

A research project to be undertaken by an Australian biotechnology company among the people of Tonga has recently received some press coverage. Statements such as ‘Tonga has become the latest country to sell the rights to its gene pool to commercial gene hunters’¹ are likely to promote community concern regarding the ethics of conducting genetic research in isolated communities.

In this article, I examine some of these concerns and touch on how the research company has tried to address them.

The project

An Australian biotechnology company has contracted with the Ministry of Health in the Kingdom of Tonga to obtain blood samples for research. The Tongan Ministry of Health will identify families with a high incidence of certain diseases particular to the region, such as early-onset diabetes and obesity.² Members of these families will be asked to donate blood for research. DNA will then be extracted from their blood and analysed at a new research centre to be built next to the public hospital. The DNA will be stored at the research centre.

The purpose of the research is to try to find correlations between particular genes and the onset of disease. This, in turn, will assist in the development of new drugs and, eventually, drugs specific to people with a particular genetic constitution.

For three reasons, I believe this project is not a sale of rights to the gene pool of the people of Tonga. Firstly, the biotechnology company will not be paying donors for blood or DNA.³ Donors will be unpaid volunteers, all of whom will have been informed and given consent before any samples are taken. Samples will be stored anonymously, and will be owned by the Tongan government.⁴

Secondly, blood will not be taken from

the whole population (the gene pool) of Tonga, but only from members of families who are affected by particular diseases.

Thirdly, the biotechnology company will not own the samples. It will acquire an exclusive right of access to the stored blood, in order to undertake research for a limited period of time. Some people may object to an exclusive right of access, as they do to patents on biological substances; however, it should be remembered that the right of access is not ownership and is only for a limited period of time.

Could this research be exploitation?

Some people are concerned about the ethics of conducting research on members of remote communities. These communities are perceived as being vulnerable to exploitation by researchers from developed countries acting for their own advantage.

In response to such concerns, I would point out that Tonga was chosen for the following reasons:

- Tonga is historically, geographically and genetically isolated, thus making its population homogenous, unlike populations elsewhere in the world.
- The Tongan people have ‘exceptional local knowledge of genealogical blood ties’.² As Autogen scientist Professor Greg Collier put it: ‘Tonga has a lot of history in their family groupings; they know who is related to whom’.⁵
- There is a high prevalence of particular diseases in Tonga.

Furthermore, there is no compulsion on the people of Tonga to participate in the research. Only informed and consenting volunteers will be involved in the research.

Finally, exploitation implies that the exploiting party will gain a benefit compared with, or a much greater benefit than, the party exploited. It is true that if the research is successful, the biotechnology company hopes to develop and

Professor Skene is Professor of Law, Faculty of Law, Faculty of Medicine, Dentistry and Health Sciences, and Project Director, Centre for Applied Philosophy and Public Ethics, University of Melbourne, Melbourne, Vic.

Dr Paul Nisselle is Chief Executive, Medical Indemnity Protection Society, Carlton, Vic.

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commercialise drugs for Western countries to treat conditions like diabetes, cardiovascular disease, hypertension, and various cancers. That is the purpose of research and development in the pharmaceutical industry and the primary reason for investing in it. However, this project also has important potential benefits for the Tongan people, both as a community and individually. Apart from funding for research and improved research facilities, volunteers will gain information about familial mutations and the implications for disease for themselves and their families, as well as access to drugs stemming from the research.

What safeguards are in place?

The biotechnology company has stated that its research will comply with the NHMRC's 'National statement on ethical conduct in research involving humans'. In particular, 'Ethics approval for any projects will be obtained through a recognised Human Ethics Committee in Australia and a Human Ethics Committee in any country from which samples are to be collected'.⁶ Information will be encrypted, kept secure and confidential. Ethics approval and monitoring will be up to Australian standards.

Concluding remarks

While the biotechnology company will clearly benefit from such a project, there are also benefits for the Tongan community (e.g. information for families about familial mutations and implications for disease), as well as the wider community.

Given that only informed volunteers are involved, and the biotechnology company's undertaking to ensure research meets ethical standards, it seems the benefits of such research outweigh the potential harms.

Series Editor's comment

Population studies almost invariably hit a brick wall – a barrier between ethical

requirements and the collection of meaningful data. If you want to conduct a whole population study but only use patients who consent to be involved, how can you be sure that those who refuse are as randomised as those who participate in the study? What if removing those who refuse from the total skews the remaining sample?

For example, some studies relating 'promiscuity' (now there's a value-laden word) to cervical cancer suggest that people who are faithful members of certain religious groups are less at risk because they are less promiscuous. If you are a member of such a group, you may feel too guilt ridden to be able to admit to a researcher that you are or have been promiscuous. Will we ever know if orthodox Jewish women have less cervical cancer because their husbands are circumcised or because both husbands and wives are (self-) reportedly highly monogamous? Similarly, research on a link between alcohol and tobacco consumption and low weight babies is entirely dependent on respondents reporting their consumption honestly.

Some epidemiological research has been proposed on blood collected for transfusion. Small aliquots could be taken, denominated, and then used for research. To the extent that blood donors are representative of the whole population (an assumption I think is tenuous), this may avoid self-selection and self-exclusion, but there remain two major problems.

First, the blood is being used for a purpose other than that intended by the donors. (Would a 'blanket' consent, such as 'I agree for my donated blood to be used for transfusion purposes or any other treatment or research purpose' be lawful?)

Second, what if an abnormality is detected indicating either disease in the donor or a risk to the community from the use of that donor's blood. 'Easy', some might say, 'Just ensure an independent third party holds the code to

the numbering system so that the original donor can be traced.' However, the original consent would then be flawed unless it specifically mentioned the possibility of back-identification of the donor. If it did, some people would refuse to participate and we're back to skewing of the sample.

Much of the research we have relied heavily on over the years has now been shown to be flawed by skewed samples. An obvious area is work conducted using military personnel. The sex, colour and religious balance of the military is clearly not the same as in the broader community. How relevant then are the findings of such research for the rest of us? How relevant is genetic research on diabetes and obesity on self-selected Tongans either to the rest of the community or to the Tongans who choose not to enter the study?

None of this is new to the ethics committees which approve or veto research proposals, but it is especially relevant to whole-population studies. Can meaningful epidemiological data be collected ethically? MT

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